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U.S. DISTRICT COURT
N.D. OF ALABAMA

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
EASTERN DIVISION

TOWN OF MUNFORD ALABAMA, a municipal corporation,

Plaintiff,

v.

CARDINAL HEALTH, INC., AMERISOURCEBERGEN DRUG CORPORATION, MCKESSON CORPORATION, ACTAVIS, LLC, ACTAVIS PHARMA, INC., ACTAVIS PLC, ALLERGAN PLC, CEPHALON, INC., ENDO HEALTH SOLUTIONS, INC., ENDO PHARMACEUTICALS, INC., INSYS THERAPEUTICS, INC., JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA, INC., JOHNSON & JOHNSON, MALLINCKRODT, PLC, MALLINCKRODT, LLC, NORAMCO, INC., ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC., PURDUE PHARMA, INC., PURDUE PHARMA, L.P., THE PURDUE FREDERICK COMPANY, TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., WATSON LABORATORIES, INC.,

Defendants.

Case No.:

DEMAND FOR JURY TRIAL

COMPLAINT

I. INTRODUCTION

1. Plaintiff Town of Munford, Alabama ("Plaintiff" or "Town"), provides essential services on behalf of its residents, including services for families and children, public assistance, medical assistance, public welfare, law enforcement, and other care and services for the health,

safety, and welfare of its residents.

2. Plaintiff depends on the health, welfare, and productivity of its resident workforce to maintain a safe environment and to support the local economy generating revenue to pay taxes for the public good. Plaintiff has sustained injury as a result of Defendants' illegal and wrongful conduct alleged herein.

3. Plaintiff brings this suit against the manufacturers of prescription opioids. The manufacturers aggressively pushed highly addictive, dangerous opioids, falsely representing to doctors that patients would only rarely succumb to drug addiction. These pharmaceutical companies aggressively advertised to and persuaded doctors to prescribe highly addictive, dangerous opioids, which turned patients into drug addicts for their own corporate profit. Such actions were intentional and/or unlawful.

4. Plaintiff also brings this suit against the wholesale distributors of these highly addictive opioid drugs. The distributors and manufacturers intentionally and/or unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of prescription opiates thereby allowing opioids to flood the marketplace including in the Town of Munford.

II. BACKGROUND

A. OVERVIEW OF OPIOIDS.

5. The term "opioids" include brand-name drugs like OxyContin and Percocet as well as generics like oxycodone and hydrocodone. These drugs are derived from or possess properties similar to opium and heroin, and, as such, they are highly addictive and dangerous. Opioids are regulated by the United States Food and Drug Administration ("FDA") as controlled substances.

6. Opioids are not intended for long-term use. Taken outside limited doses for short-

term pain relief, opioids are addictive and destructive. Opioids are effective treatment for short-term post-surgical and trauma-related pain, and for palliative end-of-life care. Opioids are far too addictive and too debilitating for long-term use for chronic non-cancer pain lasting three months or longer ("chronic pain").

7. Opioids have been approved by the FDA for use in the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. Defendants, however, have manufactured, promoted, and marketed opioids for the management of pain by misleading consumers and medical providers through misrepresentations or omissions regarding the appropriate uses, risks, and safety of opioids.

8. It is commonly understood within the study of pharmacology, medical professionals, and research studies that the effectiveness of opioids wanes over time, which requires increases in doses to achieve pain relief. Usage over time markedly increases the risk of significant side effects and addiction.[1] Defendants knew that, in their controlled studies of the safety and efficacy of opioids, the risk of addiction and other adverse outcomes were significantly minimized.

9. Opioids are a controlled substance, and Alabama law categorizes them as having a "high potential for abuse." *See* ALA. CODE § 20-2-24(1)(a). These "Schedule II" drugs are controlled substances with a "high potential for abuse," 21 U.S.C.A. §§ 812(b), 812(2)(A)-(C).

10. Opioid use often leads users to use heroin when their access to prescription opioids becomes limited. Heroin is pharmacologically similar to prescription opioids. The majority of current heroin users report having used prescription opioids non-medically before they initiated heroin use. Available data indicates that the nonmedical use of prescription opioids is a strong risk

[1] Addiction includes a broad spectrum of substance use disorders ranging from misuse and abuse of drugs to addiction. Throughout this Complaint, "addiction" refers to the entire range of substance abuse disorders. Individuals suffer negative consequences wherever they fall on the substance use disorder spectrum.

factor for heroin use.[2] Since 1999, overdose deaths caused by prescription opioids have skyrocketed, and induced a massive rise in heroin and other opioid deaths. The CDC reports that overdose deaths involving heroin have more than tripled in the last four years, and the opioid epidemic is largely to blame.[3]

11. The rising numbers of people addicted to opioids have led to significantly increased healthcare costs as well as a dramatic increase in social problems, including drug abuse and diversion and the commission of criminal acts to obtain opioids throughout the United States. The Centers for Disease Control and Prevention (CDC) recently estimated that the total "economic burden" of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of health care, lost productivity, addiction treatment, and criminal justice involvement. Consequently, public health and safety throughout the United States has been significantly and negatively impacted due to the misrepresentations and omissions by Defendants regarding the appropriate uses and risks of opioids, ultimately leading to widespread inappropriate use of the drug.

B. SCHEME TO DECEIVE BY THE MANUFACTURER DEFENDANTS.

12. In order to expand the market for opioids and realize increased profits, Manufacturer Defendants[4] sought to create a false perception of the safety and efficacy of opioids in the minds of medical professionals and members of the public that would encourage the use of opioids for longer periods of time and to treat a wide range of problems, including such common aches and pains as lower back pain, arthritis, and headaches.

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[2] *See* Wilson M. Compton, *Relationship Between Nonmedical Prescription-Opioid Use and Heroin*, 374 N. Eng. J. Med. 154 (2016).

[3] Theodore Cicero, Matthew Ellis, Hilary Surratt, The Changing Face of Heroin Use in the United States, 71 J. Am. Med. Assoc. 821 (July 2014).

[4] Manufacturer Defendants are defined, *infra*, Sec. III.

13. Manufacturer Defendants accomplished the false perception of safety and efficacy through a coordinated, sophisticated, and highly deceptive marketing campaign that began in the late 1990s and became more aggressive in or about 2006. The Manufacturer Defendants' conduct continues still today.

14. Manufacturer Defendants accomplished their marketing campaign goal by convincing doctors, patients, and others that the benefits of using opioids to treat chronic pain outweighed the risks, and that opioids could be safely used by most patients. Manufacturer Defendants, individually and collectively, knowing that long-term opioid use causes addiction, misrepresented the dangers of long-term opioid use to physicians, pharmacists, and patients by engaging in a campaign to minimize the risks of, and to encourage, long-term opioid use.

15. Opioids are now the most prescribed class of drugs. In 2012 alone, opioids generated $8 billion in revenue for drug companies. Of that amount, $3.1 billion went to Purdue for its OxyContin sales. In 2014, opioids generated $11 billion in revenue for drug companies. Overall profits collected by the Manufacturer Defendants over the relevant time frame total in the tens of billions of dollars.

16. In 2012, an estimated 2.1 million people in the United States suffered from substance abuse and/or use disorders related to prescription opioid pain relievers. Between 30% and 40% of long-term users of opioids experience problems with opioid abuse and/or use disorders. The National Institutes of Health ("NIH") not only recognize the opioid abuse problem, but also identifies Manufacturer Defendants' "aggressive marketing" as a major cause. "Several factors are likely to have contributed to the severity of the current prescription drug abuse problem. They include drastic increases in the number of prescriptions written and dispensed, greater social acceptability for using medications for different purposes, and aggressive marketing by

pharmaceutical companies."[5]

17. In 2013, in response to a petition to require manufacturers to strengthen warnings on the labels of long-acting opioid products, the FDA warned of the "grave risks" of opioids, including "addiction, overdose, and even death." The FDA further warned, "[e]ven proper use of opioids under medical supervision can result in life-threatening respiratory depression, coma, and death." Because of those grave risks, the FDA said that long-acting or extended release opioids "should be used only when alternative treatments are inadequate." The FDA required that - going forward - makers of long-acting opioid formulations clearly communicate these risks in their labels.

18. In 2016, the FDA expanded its warnings for immediate-release opioid pain medications, requiring similar changes to the labeling of immediate-release opioid pain medications as it had for extended release opioids in 2013. The FDA also required several additional safety-labeling changes across all prescription opioid products to include additional information on the risk of these medications. The facts on which the FDA relied in 2013 and 2016 were well known to Manufacturer Defendants in the 1990s when their deceptive marketing began. The Manufacturer Defendants promoted their opioid products in contradiction to the concerns stated by the FDA by aggressively promoting the idea that opioids should be taken continuously and then even supplementing them with even more opioids in the form of short-acting, rapid onset opioids for episodic pain.

19. In an open letter to the nation's physicians in August 2016, the then-U.S. Surgeon General expressly connected this "urgent health crisis" to "heavy marketing of opioids to doctors … [m]any of [whom] were even taught – incorrectly – that opioids are not addictive when

[5] America's Addiction to Opioids: Heroin and Prescription Drug Abuse. Available at http://www.drugabuse.gov/aboutnida/ legislative-activities/testimony-to- congress/2015/americas-addiction-to-opioids-heroin-prescription-drug-abuse#_ftn2

prescribed for legitimate pain." This epidemic, fueled by opioids lawfully prescribed by doctors, has resulted in a flood of prescription opioids available for illicit use or sale (the supply), and a population of patients physically and psychologically dependent on them (the demand). And when those patients can no longer afford or legitimately obtain opioids, they often turn to the street to buy prescription opioids or even heroin.

C. DISTRIBUTOR DEFENDANTS FAILED TO PREVENT THE IMPROPER DISTRIBUTION OF OPIOIDS.

20. The Distributor Defendants[6] intentionally and unlawfully breached their legal duties under federal and state law to monitor, detect, investigate, refuse and report suspicious orders of opioids. Because distributors handle such large volumes of controlled substances and are the first major line of defense in the movement of legal pharmaceutical controlled substances from legitimate channels into the illicit market, it is incumbent on distributors to maintain effective controls to prevent diversion of controlled substances.

21. The federal government and the state of Alabama each regulates the distribution of opioids for the purpose of providing a "closed" system intended to reduce the widespread diversion of these drugs out of legitimate channels into the illicit market, while at the same time providing the legitimate drug industry with a unified approach to narcotic and dangerous drug control.

22. The three largest wholesale distributors (*i.e.*, AmerisourceBergen Drug Corporation, Cardinal Health, Inc. and McKesson Corporation) share 85% of the market for the distribution of prescription opioids. These are Fortune 500 corporations listed on the New York Stock Exchange whose principal business is the nationwide wholesale distribution of prescription drugs. The DEA has investigated and/or fined each for the failure to report suspicious orders.

[6] Distributor Defendants are defined, *infra*, Sec. III.

23. Each Distributor Defendant has an affirmative duty under federal and Alabama law to act as a gatekeeper guarding against the diversion of the highly addictive, dangerous opioid drugs. Federal law requires that Distributors of Schedule II drugs, including opioids, must maintain "effective control against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels." 21 U.S.C. §§ 823(b)(1). Alabama law adopts and incorporates those requirements.

24. Federal regulations, incorporated by Alabama law, impose a non-delegable duty upon wholesale drug distributors to design and operate a system to disclose to the registrant suspicious orders of controlled substances. The Distributor Defendants are required to report all suspicious orders when discovered by the registrant.

25. Suspicious orders include those of an unusual size, orders of unusual frequency or orders deviating substantially from a normal pattern. *See* 21 CFR § 1301.74(b). If an order deviates substantially from a normal pattern, the size of the order does not matter, and the distributor should report the order as suspicious. Likewise, a distributor need not wait for a normal pattern to develop over time before determining whether a particular order is suspicious. The size of an order alone, regardless of whether it deviates from a normal pattern, is enough to trigger the wholesale distributor's responsibility to report the order as suspicious. The determination of whether an order is suspicious depends not only on the ordering patterns of the particular customer, but also on the patterns of the entirety of the wholesale distributor's customer base and the patterns throughout the relevant segment of the wholesale distributor industry.

26. The Distributor Defendants failed to report, and instead filled, suspicious orders originating from Plaintiff's community and that the Distributor Defendants knew were likely to be diverted to Plaintiff's community. These Defendants knew that filling suspicious orders that might

be diverted into channels other than legitimate medical, scientific and industrial channels could cause damage and injury to the general public including the Plaintiff. The Distributor Defendants' repeated shipments of suspicious orders over an extended period of time, in violation of public safety statutes and without reporting the suspicious orders to the relevant authorities demonstrate wanton, willful, and reckless conduct to the Plaintiff and its citizens.

27. The industry-wide opioid conspiracy has resulted in federal prosecution of drug company executives. It has also resulted in administrative fines levied to a number of Defendants. Despite the actions by law enforcement and federal agencies, the wrongful acts by Defendants continue because of the tremendous profit incentives to their companies through the manufacture, distribution and marketing of opioids.

28. One example of the Defendants' conduct is demonstrated by Insys Therapeutics, Inc., whose former CEO Michael L. Babich and five other former executives and managers are set to go to trial for their actions in relation to a scheme to bribe doctors to prescribe the company's synthetic opioid. Several former Insys employees and health care providers have pleaded guilty to felony charges around the country, including Alabama.

29. Recently, another Defendant, McKesson Corporation, admitted that it has failed to maintain control against the improper distribution of prescription opioids and was subjected to a fine of $150,000,000.00 by the Federal Government.

D. OPIOID EPIDEMIC IN TOWN OF MUNFORD, ALABAMA.

30. Plaintiff has incurred and continues to incur costs related to opioid addiction and abuse, including but not limited to, criminal justice and victimization costs, social costs, and lost productivity costs. Defendants' misrepresentations regarding the safety and efficacy of long-term opioid use proximately caused injury to Plaintiff and its residents. Moreover, Defendants failure to

stop millions of doses of opioid drugs from flowing freely into the state of Alabama, including the Town of Munford and surrounding communities, has caused substantial damages to the Plaintiff.

31. Defendants' conduct has been overwhelmingly harmful to Alabamians. Overdoses from prescription pain relievers are a driving factor in a 15-year increase in opioid overdose deaths. Deaths from prescription opioids have also quadrupled since 1999. From 2000 to 2014 nearly half a million people died from such overdoses. Seventy-eight Americans die every day from an opioid overdose. An estimated 2 million people in the United States suffer from substance use disorders related to prescription opioid pain medicines (including fentanyl), and 591,000 suffer from a heroin use disorder (not mutually exclusive).

32. Prescription opioid abuse has not displaced heroin, but rather triggered a resurgence in its use, imposing additional burdens on local governments – such as and including the Town of Munford – that address heroin use and addiction. Individuals who are addicted to prescription opioids often transition to heroin because it is a less expensive, readily available alternative that provides a similar high.

33. Alabama cities and counties, including the Plaintiff, have been hit particularly hard by the opioid epidemic. The death rate from drug overdoses has tripled between 1999 and 2015. The DEA found that the 2015 fatal drug overdose rate reached an all-time high. The Town of Munford and surrounding communities has some of the highest opioid abuse and addiction hospitalization rates as well. The opioid epidemic is particularly devastating in Plaintiff's community. Plaintiff is situated in Talladega County, Alabama, which had an opioid prescription rate of over 138.9 prescriptions per 100 persons in 2016.[7]

[7] U.S. Prescribing Rate Maps, Centers for Disease Control and Prevention (2017), https://www.cdc.gov/drugoverdose/maps/rxrate-maps.html .

34. As a result of Defendants' conduct, Plaintiff has been required to spend substantial funds each year in its efforts to combat the opioid epidemic and resulting public nuisance created by the Defendants. Categories of past and continuing damages include but are not limited to (1) costs for providing treatment, counseling and rehabilitation services; (2) costs associated with law enforcement and public safety relating to the opioid epidemic, including payments for Naloxone Hydrochloride (Narcan) resulting from opioid abuse and overdose; and (3) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation.

35. Plaintiff also seeks the means to abate the epidemic and the resultant harm and injuries Defendants' wrongful and/or unlawful conduct has created.

36. The Plaintiff has been damaged, and continues to be damaged, by the Defendants' conduct.

III. PARTIES

37. Plaintiff, Town of Munford, Alabama, is a municipal corporation organized under the laws of the State of Alabama and is authorized to bring the causes of action brought herein. ALA. CODE § 11-40-1 ("All municipal organizations now existing in the State of Alabama… shall sue and be sued…. Such municipal corporations shall be invested with the full powers, duties, and authority granted in this title."). Plaintiff is responsible for the public health, safety, and welfare of its citizens.

38. Plaintiff Town of Munford, Alabama is specifically authorized to seek common law public nuisance remedies available under Alabama law. *See* ALA. CODE § 6-5-122 ("All municipalities in the State of Alabama may commence an action in the name of the city to abate or enjoin any public nuisance injurious to the health, morals, comfort, or welfare of the community or any portion thereof."); 11-47-118 ("Municipalities may maintain a civil action to enjoin and

abate any public nuisance, injurious to the health, morals, comfort or welfare of the community or any portion thereof."); 11-47-117 ("All cities and towns of this state shall have the power to prevent injury or annoyances from anything dangerous or offensive or unwholesome and to cause all nuisances to be abated and assess the cost of abating the same against the person creating or maintaining the same.").

39. In the Town of Munford, opioid abuse, addiction, morbidity, and mortality has created a serious public health, safety crisis, and a public nuisance. The delivery, supply, and diversion of legally produced controlled substances into the illicit market causes or contributes to this public nuisance.

40. The distribution of opioids into Alabama ("the State"), has created a foreseeable opioid epidemic and opioid public nuisance for which Plaintiff seeks relief.

41. Plaintiff directly and foreseeably sustained all economic damages alleged herein. Defendants' conduct has exacted a financial burden for which Plaintiff seeks relief. Categories of past and continuing sustained damages include, *inter alia*: (1) costs for providing treatment, counseling, and rehabilitation services; (2) costs associated with law enforcement and public safety relating to the opioid epidemic; (3) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered directly, by the Plaintiff.

42. Plaintiff has standing to recover damages incurred as a result of Defendants' actions and omissions. Plaintiff has standing to bring all claims pled herein.

A. DEFENDANTS

1. Manufacturer Defendants

43. The Manufacturer Defendants are defined below. At all relevant times, the

Manufacturer Defendants have designed, manufactured, packaged, distributed, supplied, sold, placed into the stream of commerce, labeled, described, marketed, advertised, promoted, and purported to warn or purported to inform prescribers and users regarding the benefits and risks associated with the use of prescription opioid drugs. The Manufacturer Defendants, at all times, have manufactured and sold prescription opioids without fulfilling their legal duty to prevent diversion and report suspicious orders.

44. Defendant Purdue Pharma L.P. is a limited partnership organized under the laws of the State of Delaware with its principal place of business in Stamford, Connecticut.

45. Defendant Purdue Pharma, Inc. is a New York corporation with its principal place of business in Stamford, Connecticut.

46. Defendant The Purdue Frederick Company, Inc. as a New York corporation with its principal place of business in Stamford, Connecticut.

47. Defendants Purdue Pharma, L.P., Purdue Pharma, Inc., and The Purdue Frederick (collectively, "Purdue"), are engaged in the manufacture, promotion, distribution, and sale of opioids nationally and in the Plaintiff community, including OxyContin (Oxycodone hydrochloride extended release), MS Contin (Morphine sulfate extended release), Dilaudid (Hydromorphone hydrochloride), Dilaudid-HP (Hydromorphone hydrochloride), Butrans (Byrenorpine), Hysingla ER (Hyrdrocodone bitrate), and Targiniq ER (Oxycdone hydrocholoride and Naloxone hydrochloride), all of which except Butrans are Schedule II.[8]

[8] Since passage of the Controlled Substances Act ("CSA") in 1970, opioids have been regulated as controlled substances. As controlled substances, they are categorized in five schedules, ranked in order of their potential for abuse, with Schedule I being the most dangerous. The CSA imposes a hierarchy of restrictions on prescribing and dispensing drugs based on their medicinal value, likelihood of addiction or abuse, and safety. Opioids generally have been categorized as Schedule II or Schedule III drugs. Schedule II drugs have a high potential for abuse, have a currently accepted medical use, and may lead to severe psychological or physical dependence. Schedule III drugs are deemed to have a lower potential for abuse, but their abuse still may lead to moderate or low physical dependence or high psychological dependence. Of the Purdue drugs listed above, Butrans is the only Schedule III drug.

48. OxyContin is Purdue's largest-selling opioid. Since 2009, Purdue's national annual sales of OxyContin have fluctuated between $2.47 billion and $2.99 billion, up four-fold from 2006 sales of $800 million. OxyContin constitutes roughly 30% of the entire market for analgesic drugs (*i.e.*, painkillers).

49. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business in North Wales, Pennsylvania. Teva USA is a wholly owned subsidiary of Teva Pharmaceutical Industries, Ltd. ("Teva Ltd."), an Israeli corporation.

50. Defendant Cephalon, Inc. is a Delaware corporation with its principal place of business in Frazer, Pennsylvania. In 2011, Teva Ltd. acquired Cephalon. Inc.

51. Teva USA and Cephalon, Inc. (collectively, "Cephalon") work together to manufacture, promote, distribute and sell both brand name and generic versions of opioids nationally and in Alabama, including Actiq (Fentanyl citrate) and Fentora (Fentanyl citrate tablet), both Schedule II drugs.

52. Teva USA was in the business of selling generic opioids, including a generic form of OxyContin from 2005 to 2009 nationally and in Alabama.

53. Defendant Allergan PLC, f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc., is a public limited company incorporated in Ireland with its principal place of business in Dublin, Ireland. Actavis PLC acquired Allergan PLC in March 2015, and the combined company changed its name to Allergan PLC in January 2013. Before that, in October 2012, Watson Pharmaceuticals, Inc. acquired Actavis, Inc., and the combined company changed its name to Actavis, Inc. as of January 2013, and then Actavis PLC in October 2013. Defendant Watson Laboratories, Inc. is a Nevada corporation with its principal place of business in Corona, California and is a wholly-

owned subsidiary of Allergan PLC (f/k/a Actavis, Inc., f/k/a Watson Pharmaceuticals, Inc.). Defendant Actavis Pharma, Inc., f/k/a Watson Pharma, Inc., is a Delaware corporation with its principal place of business in New Jersey and was formerly known as Watson Pharma, Inc. Defendant Actavis, LLC is a Delaware limited liability company with its principal place of business in Parsippany, New Jersey. Defendant Allergan PLC owns each of these defendants and uses them to market and sell its drugs in the United States. Upon information and belief, Allergan PLC exercises control over these marketing and sales efforts and profits from the sale of Allergan/Actavis products that ultimately inure to its benefit. Defendants Allergan PLC, f/k/a Actavis, Inc. f/k/a Watson Pharmaceuticals, Inc.; Actavis PLC, Watson Laboratories, Inc.; Actavis Pharma, Inc., f/k/a Watson Pharma, Inc.; and Actavis LLC are referred to as "Actavis."

54. Actavis manufactures, promotes, distributes, and sells the branded opioids Kadian (morphine sulfate extended release) in Alabama and within Plaintiff's community. Kadian is a Schedule II drug. Actavis also sells a generic version of Kadian, Duragesic, and Opana. Actavis acquired the rights to Kadian from King Pharmaceuticals, Inc., on December 30, 2008 and began marketing Kadian in 2009.

55. Defendant Janssen Pharmaceuticals, Inc. ("Janssen Pharmaceuticals") is a Pennsylvania corporation with is principal place of business in Titusville, New Jersey. Janssen Pharmaceuticals, Inc. was formerly known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was formerly known as Janssen Pharmaceutica, Inc.

56. Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc., n/k/a Janssen Pharmaceuticals, Inc., is a Pennsylvania corporation with its principal place of business in Titusville, New Jersey.

57. Janssen Pharmaceuticals is a wholly owned subsidiary of Defendant Johnson &

Johnson (J&J), a New Jersey corporation with its principal place of business in New Brunswick, New Jersey.

58. Defendant Noramco, Inc. ("Noramco") is a Delaware company headquartered in Wilmington, Delaware and was a wholly owned subsidiary of J&J until July 2016.

59. J&J is the only company that owns more than 10% of Janssen Pharmaceuticals' stock and corresponds with the FDA regarding Janssen's products. Upon information and belief, J&J controls the sale and development of Janssen Pharmaceuticals' drugs and Janssen's profits inure to J&J's benefit (Janssen Pharmaceuticals, Inc., Ortho-McNeil- Janssen Pharmaceuticals, Inc., Janssen Pharmaceutica, Inc., Noramco, and J&J are referred to collectively as "Janssen").

60. Janssen manufactures, promotes, sells and distributes drugs in the United States, including the opioid Duragesic (fentanyl). Before 2009, Duragesic accounted for at least $1 billion in annual sales. Until January 2015, Janssen developed, marketed and sold the opioids Nucynta (tapentadol) and Nucynta ER. Together, Nucynta and Nucynta ER accounted for $172 million in sales in 2014.

61. Defendant Insys Therapeutics, Inc. ("Insys") is a Delaware Corporation with its principal place of business in Scottsdale, Arizona.

62. Defendant Mallinckrodt, PLC is an Irish public limited company headquartered in Staines-upon-Thames, United Kingdom, with its United States headquarters in St. Louis, Missouri.

63. Mallinckrodt, LLC is a limited liability company organized and existing under the laws of the State of Delaware. Mallinckrodt, LLC is a wholly owned subsidiary of Mallinckrodt, PLC. Mallinckrodt, PLC and Mallinckrodt, LLC are referred to as "Mallinckrodt."

64. Mallinckrodt manufactures, markets and sells drugs in the United States including generic oxycodone, of which it is one of the largest manufacturers. In July 2017, Mallinckrodt

agreed to pay $35 million to settle allegations brought by the Department of Justice that it failed to detect and notify the DEA of suspicious orders of controlled substances.

65. Endo Health Solutions, Inc. is a Delaware corporation with its principal place of business in Malvern, Pennsylvania. Endo Pharmaceuticals, Inc. is a wholly owned subsidiary of Endo Health Solutions, Inc. and is a Delaware corporation with its principal place of business in Malvern, Pennsylvania (Endo Health Solutions, Inc. and Endo Pharmaceuticals, Inc. are referred to collectively as "Endo").

66. Endo develops, markets and sells prescription drugs, including the opioids Opana/Opana ER, Percodan, Percocet and Zydone, in the United States. Opioids made up roughly $403 million of Endo's overall revenues of $3 billion in 2012. Opana ER yielded $1.15 billion in revenue from 2010 and 2013 and accounted for 10% of Endo's total revenue in 2012. Endo also manufactures and sells generic opioids, such as oxycodone, oxymorphone, hydromorphone and hydrocodone products, in the United States, by itself and through its subsidiary, Qualitest Pharmaceuticals, Inc.

2. Distributor Defendants

67. The Distributor Defendants are defined below. At all relevant times, the Distributor Defendants have distributed, supplied, sold, and placed into the stream of commerce prescription opioids, without fulfilling the fundamental duty of wholesale drug distributors to detect and warn of diversion of dangerous drugs for non-medical purposes. The Distributor Defendants universally failed to comply with federal and/or state law. The Distributor Defendants are engaged in "wholesale distribution," as defined under state and federal law. Plaintiff alleges the unlawful conduct by the Distributor Defendants is responsible for the volume of prescription opioids plaguing Plaintiff's Community.

68. Defendant McKesson Corporation ("McKesson") is registered with the Alabama Secretary of State as a Delaware corporation which may be served through its registered agent for service of process, Corporation Service Company, 641 South Lawrence Street, Montgomery, Alabama 36104. McKesson Corporation has its principal place of business located in San Francisco, California. McKesson operates distribution centers in Alabama, including in McCalla, Alabama.

69. McKesson promotes, distributes, and sells opioids manufactured by Manufacturers across the country and, upon information and belief, within Alabama and the Plaintiff's community to pharmacies and institutional providers. It had a net income over $1.5 billion in 2015.

70. Defendant Cardinal Health, Inc. ("Cardinal") is an Ohio Corporation with its principal office in Dublin, Ohio. Cardinal Health, Inc., operates distribution centers in Alabama, including in Birmingham, Alabama.

71. Defendant AmerisourceBergen Drug Corporation ("Amerisource") is registered with the Alabama Secretary of State as a Delaware Corporation which may be served through its registered agent for service of process, CT Corporation System, 2 North Jackson Street, Suite 605, Montgomery, Alabama 36104. AmerisourceBergen Drug Corporation's principal place of business is located in Chesterbrook, Pennsylvania. AmerisourceBergen Drug Corporation operates distribution centers in Alabama, including in Pelham, Alabama.

72. All Defendants do business by agent in Alabama and are part of a series of distribution agreements providing opioid drugs to distribution centers, pharmacies, and healthcare professionals through the State of Alabama and in the Plaintiff's community.

IV. JURISDICTION AND VENUE

73. This Court has subject matter jurisdiction under 28 U.S.C. § 1331 based upon the federal claims asserted under the Racketeer Influenced and Corrupt Organizations Act, 18 U.S.C.

§ 1961, *et seq*. ("RICO"). This Court has supplemental jurisdiction over Plaintiff's state law claims pursuant to 28 U.S.C. § 1367 because those claims are so related to Plaintiff's federal claims that they form part of the same case or controversy

74. This Court also has jurisdiction over this action in accordance with 28 U.S.C. § 1332(a) because Plaintiff is a "citizen" of this State, the named Defendants are citizens of different states and the amount in controversy exceeds the sum or value of $75,000, exclusive of interest and costs.

75. This Court has personal jurisdiction over Defendants because they conduct business in the State, they purposefully direct or directed their actions toward the State, some or all consented to be sued in the State by registering an agent for service of process, they consensually submitted to the jurisdiction of the State when obtaining a manufacturer or distributor license and they have the requisite minimum contacts with the State necessary to constitutionally permit the Court to exercise jurisdiction.

76. Venue is proper in this District pursuant to 28 U.S.C. § 1391 and 18 U.S.C. §1965 because a substantial part of the events or omissions giving rise to the claims stated herein occurred in this District and each Defendant transacted affairs and conducted activity that gave rise to the claims for relief in this District. 28 U.S.C. § 1391(b); 18 U.S.C. §1965(a).

COUNT I
(NEGLIGENCE)

77. All allegations and paragraphs in this complaint are incorporated by reference. To the extent necessary, this cause of action is pleaded in the alternative to the other causes of action.

78. The Defendants owe a duty to use reasonable care to prevent causing harm to the Plaintiff resulting from the Defendants' marketing, distribution, delivery, and sale of prescription opioids in Alabama and particularly in the Town of Munford's community.

79. The Defendants also owe a duty to the Plaintiff to maintain all appropriate licensing in Alabama to distribute prescription opioids, to investigate and report on improper, suspicious and illegal orders, and to prevent and stop any and all illegitimate shipments and distributions of opioids into Alabama.

80. The Defendants are further under a legal duty to protect the health and welfare of the citizens of Alabama by following federal and state laws concerning misuse and abuse of controlled substances.[9]

81. Rather than uphold and follow their duties as set forth above, imposed by statute and at common law, the Defendants, individually and collectively, worked to breach their duties, both directly and by subterfuge, artifice and deception. The Defendants' breach of duty in many cases is willful, reckless, wanton and in total disregard of the safety of the general public including the citizens of the Plaintiff.

82. As a result of the Defendants' breach of their legal duties, Alabama suffers the highest rate of prescription opioid usage in America at 121 prescriptions per 100 people. Prescription rates of benzodiazepine and other synthetic opioids are at equally high rates in Alabama. The volume of prescription opioids written, sold, shipped and delivered by Defendants to Plaintiff's community is beyond the amount that a reasonably prudent corporate entity would provide under similar circumstances given the applicable regulations and knowledge available to Defendants.

83. Defendants' marketing and promotion of their opioid prescription drug products is inconsistent and contrary to the actions of reasonably prudent corporate entities under similar

[9] Ala. Code §§ 20-2-52, § 20-2-56, § 20-2-57, and Alabama Administrative Code §§ 680-X-3.05, § 680-X-2-.23(k)(3), and laws incorporated therein, including federal controlled substance laws, which are public safety laws. The Alabama Legislature has found that "the division, abuse, and misuse of prescription medications classified as controlled substances under the Alabama Uniform Controlled Substances Act constitutes a serious threat to the health and welfare of the citizens of the State of Alabama." ALA. CODE § 20-2-210.

circumstances given the applicable knowledge and information of Defendants that they have created an opioid drug crisis across America and in Plaintiff's community. Instead of exercising caution, issuing reports to federal, state, and local governments about out of control opioid distribution and use, the Defendants actively worked to sell and distribute more prescription opioids without regard for the consequences and damages being caused to the Plaintiff.

84. Defendants know that there is a strong connection between abuse of prescription opioids and the use of heroin. The strongest and most direct indicator of heroin usage is introduction to, and abuse of, prescription opioids. Government studies have linked the use and abuse of prescription painkillers to the growing use of heroin and the resulting occurrence of overdoses and deaths from heroin.

85. Defendants' breach of duty and failure to use reasonable care in the distribution, investigation, reporting, marketing, delivery, and sale of prescription opioids have led to the resulting heroin abuse and addiction experienced by Plaintiff's citizens, in addition to the illegal distribution of prescription opioids in Plaintiff's community.

86. As a result of Defendants' breach of duty and failure to use reasonable care, Plaintiff has been and continues to be damaged through the rampant distribution of prescription opioids that Defendants were under a duty to monitor and control, but instead enabled, expanded and participated in the wrongful distribution of their products.

87. As a proximate result of Defendants' conduct, Plaintiff has been damaged, and will continue to be damaged, and seeks full compensatory as well as punitive damages where applicable, for its damages including the following:

a. The Plaintiff has expended substantial sums of money and will continue to expend substantial sums of money to deal with the skyrocketing costs for

continued treatment and abatement of opioid addiction;

b. The Plaintiff has expended resources and funding for treatment facilities, counseling, law enforcement, and child and family services all directly related to opioid abuse and addiction;

c. The Plaintiff has and will continue to incur costs for jails, medical treatment, and diagnosis of those placed in its care and custody as a result of opioid use, abuse, and addiction;

d. The Plaintiff has incurred damages, and will continue to incur damages, resulting from loss of productivity from its workforce translating to loss of tax revenue and economic development;

e. As a proximate result of the Defendants' conduct, the Plaintiff has sustained, and will continue to sustain, damages in the form of skyrocketing costs for law enforcement services, payments for Narcan resulting from opioid abuse and overdose, costs for treatment and cure of those addicted to opioids, and related addiction-based costs; and

88. Plaintiff seeks all legal and equitable relief as allowed by law, other than such damages disavowed herein, including, *inter alia,* injunctive relief, restitution, disgorgement of profits, compensatory and punitive damages, all damages allowed by law to be paid by the Defendants, (1) costs for providing treatment, counseling, and rehabilitation services; (2) costs associated with law enforcement and public safety relating to the opioid epidemic; (3) and costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation; (4) court fees and costs, and (5) pre- and post-judgment interest.

COUNT II
(DRUG-RELATED NUISANCE ALABAMA CODE § 6-5-155, et seq.)

89. All allegations and paragraphs in this complaint are incorporated by reference. To the extent necessary, this cause of action is pleaded in the alternative to the other causes of action.

90. The opioid epidemic in America has resulted in increased costs to cities and counties to address public health issues, as well as the added financial costs associated with law enforcement and the legal system.

91. As stated herein, Defendants' actions in the marketing, presentation, representation, distribution, advertising, and sale of prescription opioids has created consumption of opioid related drugs that has become dangerous and harmful to the public welfare. Prescription opioid abuse has led to increased crime and criminal activity in the State of Alabama, as well as in Plaintiff's community.

92. In Plaintiff's community, the nationwide opioid epidemic has been especially damaging, impacting people from all walks of life from newborns to the elderly, including all races and socio-economic levels of the population.

93. Alabama recognizes that drugs can have a tremendous negative impact on communities such as the Town of Munford. The Alabama Code defines a "Drug-Related Nuisance" as the "sale, distribution, possession, storage, transportation or manufacture of any controlled substance in violation of the controlled substances acts, or similar act of the United States or any other state" that causes harm to a community. Ala. Code § 6-5-155.

94. There is a duty and corresponding right provided under Alabama law for cities and counties to take action against drug related nuisances to "file an action in the circuit courts of this state to abate, enjoin, and prevent the drug-related nuisance." Ala. Code § 6-5-155.2.

95. As a result of the drug-related nuisance created by Defendants, and as elaborated in

the preceding paragraphs, the Plaintiff has sustained damages, harm and unreasonable jeopardy to the health, morals, comfort, welfare, and safety of its community and to its residents.

96. Defendants' conduct is ongoing and persistent, and Plaintiff seeks to recover all damages flowing from Defendants' conduct; including, but not limited to, abatement of the nuisance and all harm created by the Defendants' conduct, including:

a. expenses for police protection;

b. expenses for emergency response;

c. healthcare costs and expenses (including increased cost of child endangerment, emergency room care and ambulance service);

d. criminal prosecution and expenses;

e. jail and correctional expenses;

f. counseling costs and programs;

g. financial costs in caring for addiction treatment;

h. loss of value of production and tax-based revenue from a non-opioid dependent workforce;

i. direct harm to the Plaintiff;

j. all damages stemming from opioid related damages to the public health, including law enforcement, municipal and county financial resources that could otherwise have been put to necessary public use and damages relating to all entitled equitable relief;

k. attorneys' fees and costs; and

l. daily statutory fines as provided under Alabama law, including Ala. Code § 6-5-155.7.

97. In addition to the compensatory and statutory damages sought above for actual damages and abatement costs, Plaintiff claims the right to be compensated in punitive damages against all Defendants as a result of their deliberate and intentional actions committed with malice and oppression and with knowledge that their actions would likely result in grave harm to Plaintiff and its residents.

COUNT III
(FRAUD AND MISREPRESENTATION)

98. All allegations and paragraphs in this complaint are incorporated by reference. To the extent necessary, this cause of action is pleaded in the alternative to the other causes of action.

99. This Count is brought pursuant to Alabama Code §§ 6-5-101 to 6-5-104 (Code, 1975).

100. Defendants have separately and severally committed misrepresentation, deceit, concealment and fraud. Defendants have separately and severally committed fraud and misrepresentation through:

a. the willful, reckless or mistaken representations of materials facts;

b. the suppression of material facts that Defendants were under a duty to communicate;

c. the concealment of material facts with the intent to deceive and mislead;

d. the misrepresentation of material facts made willfully to induce actions to Plaintiff's detriment; and

e. the intentional misrepresentation of material facts with knowledge of the falsity of the representations with intent that Plaintiff would rely on the representations to its detriment.

101. In an effort to mislead the public concerning risks, benefits and safety of prescription

opioids, Defendants worked both individually and in concert to deceptively market and falsely present their products.

102. Similar to the deceptions inflicted on the American public by the tobacco companies denying the addictive nature of smoking and the serious adverse health effects caused by smoking, Defendants have worked in concert to minimize the addictive aspects of opioids and the serious adverse consequences of using prescription opioids.

103. Through their actions and marketing efforts to the public, patients, and healthcare professionals, including hospitals, doctors, and nurses, Defendants spent millions of dollars to conduct a campaign of fraudulent misrepresentations, which included the following:

a. misrepresenting and misleading the truth about opioids and addiction;

b. misrepresenting that opioids improve function;

c. misrepresenting that opioid dependency can be managed;

d. misrepresenting that opioid prescriptions do not create dependency leading to illegal street drugs;

e. misrepresenting that opioids should be used for more than very short periods of time, and could be used as treatment or management of chronic pain;

f. misrepresenting, fraudulently suppressing, and/or failing to disclose that Defendants had funded alleged "independent research" to support their misrepresentations and fraudulent claims concerning the effectiveness of opioid derivatives to prevent or minimize addiction risks;

g. misrepresenting that opioid withdrawal could be easily and simply managed;

h. falsely and fraudulently stating that opioid dosage posed no significant risks to patients; and

i. falsely and fraudulently suppressing the serious adverse effects of opioids while overstating the risks and potential complications from use of alternative forms of pain treatment.

104. Defendants' fraud and misrepresentation has exacted a financial burden for which Plaintiff seeks relief and damages. Categories of past and continuing sustained damages include, *inter alia*,; (1) costs for providing treatment, counseling, and rehabilitation services; (2) costs associated with law enforcement and public safety relating to the opioid epidemic; and (3) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered directly, by the Plaintiff.

105. As a direct and proximate result of Defendants' fraud and misrepresentation directed at the general public, including the Plaintiff and surrounding community, Plaintiff seeks all damages, including compensatory and punitive, to which it is entitled by law together with attorneys' fees and costs of this action.

COUNT IV
(PUBLIC NUISANCE)

106. All allegations and paragraphs in this complaint are incorporated by reference. To the extent necessary, this cause of action is pleaded in the alternative to the other causes of action.

107. Plaintiff has standing to pursue nuisance claims against the Defendants for public nuisance pursuant to Ala. Code § 6-5-121 (1975).

108. The citizens of the Plaintiff have the right to be protected from dangers to the public health, safety and welfare resulting from a public nuisance.

109. Pursuant to Alabama law, a nuisance includes "anything that works hurt, inconvenience or damage to another" and a public nuisance is defined as anything "which damages

all persons who come within the sphere of its operation, though it may vary in its effects on individuals." Ala. Code § 6-5-121 and 122 (1975).

110. Defendants, individually as well as acting through their agents, and in concert with one another, have created an opioid epidemic that has created harm, damage and inconvenience to Plaintiff and its residents. Although the effects of the nuisance created by Defendants may vary on individuals within Plaintiff's community, Defendants have created a nuisance, and damaged the public by engaging in the following conduct:

a. creating, financing and supporting the distribution of patient and prescriber education materials misrepresenting data concerning the safety and efficacy of opioids for long-term treatment of chronic non-cancer pain, including the known rates of abuse and addiction and the lack of validation of the same for long-term efficacy;

b. developing and disseminating misleading scientific studies concluding the safety of opioids for long-term treatment of chronic non-cancer pain;

c. developing and disseminating misleading scientific studies based on incomplete or inadequate data while concealing facts about the danger of prescription opioids;

d. sponsoring, distributing and assisting in the distribution of publications presenting an unbalanced presentation of the long-term dose and dependent risks of opioids versus alternatives;

e. creating, sponsoring and distributing patient education materials to consumers containing deceptive statements about opioid use;

f. marketing opioid drugs as safe and effective for long-term treatment of chronic pain conditions when they were not safe, for the purpose of deceiving physicians into using

and prescribing addictive opioid drugs to their patients;

g. distributing brochures to doctors, patients and law enforcement officials that included statements concerning the indicators of possible opioid abuse;

h. disseminating misleading statements regarding the true risk of addiction and promoting the concept of pseudoaddiction through Defendants' own unbranded publications on internet sites, operated by Defendants, directed to care givers, consumers and healthcare professionals;

i. acting intentionally, recklessly and unlawfully in failing to maintain controls against prescription opioid diversion through monitoring, reporting and in recognition of Defendants' duty to refuse to fill suspicious orders of opioids;

j. by filling suspicious and unwarranted orders of prescription opioids, and failing to maintain effective controls against drug diversion and unlawfully continuing the shipment of prescription opioids to Plaintiff's community; and

k. marketing, distributing and selling prescription opioids which Defendants knew, or should have known, were being diverted for non-legitimate, non- medical use, with a substantial likelihood of illegal and improper distribution to the public.

111. Defendants' actions are continuing in nature and as a result of said actions, the Defendants have negatively impacted the right of the citizens of the Plaintiff to live without unreasonable interference to the public health, safety, welfare, peace, comfort and convenience, unreasonable threat of crime, and the right to be free from disturbance without the unreasonable apprehension of danger to personal property resulting from the opioid epidemic.

112. Defendants' actions, separate and severally, have been, and continue to be, a substantial factor in opioids becoming widely available and widely used for non-medical purposes.

Defendants, separately and severally, have a responsibility, and legal obligation, within the system of opioid distribution to refrain from conduct that would create a widespread nuisance which includes Plaintiff's community, creating an enormous public health crisis resulting from the overuse of prescription opioids and heroin.

113. Defendants' conduct is a direct and proximate cause of death, injury, and damage to the residents of the Plaintiff, and if allowed to continue unabated it will continue to threaten the health, safety, and welfare of the its citizens.

114. The Defendants' conduct is ongoing and persistent, and the Plaintiff seeks to recover all damages flowing from Defendants' conduct; including, but not limited to, abatement of the nuisance and all harm created by Defendants' conduct, *to wit*:

a. expenses for police protection;

b. expenses for emergency response;

c. healthcare costs and expenses (including increased cost of child endangerment, emergency care, and ambulance service);

d. criminal prosecution and expenses;

e. jail and correctional expenses;

f. counseling costs and programs;

g. financial costs in caring for addiction treatment;

h. loss of value of production and tax-based revenue from of a non-opioid dependent workforce;

i. direct harm to Plaintiff;

j. all damages stemming from opioid related damages to the public health, including law enforcement, municipal and county financial resources that

could otherwise have been put to necessary public use and damages relating to all entitled equitable relief; and

k. attorneys' fees and costs.

115. In addition to the compensatory damages sought above for actual damages and abatement damages, Plaintiff claims the right to be compensated in punitive damages against Defendants as a result of their deliberate and intentional actions committed with malice and oppression and with the knowledge that their actions would likely result in grave harm.

COUNT V
(CIVIL CONSPIRACY)

116. All allegations and paragraphs in this complaint are incorporated by reference. To the extent necessary, this cause of action is pleaded in the alternative to the other causes of action.

117. Alabama law recognizes a civil conspiracy cause of action where multiple parties act in concert to commit wrongful acts. The Manufacturer and Distributor Defendants have in the past, and continue through the present, to work in a concerted effort to profit from the sale of prescription opioid drugs through violations of their statutory duties under the Controlled Substances Act, 21 U.S.C. § 801(2), 21 U.S.C. § 821-824 and 21 U.S.C. § 823(6)(1).

118. Defendants, separately and severally, encouraged their wholesalers and pharmacists to purchase ever increasing amounts of prescription opioids, and to increase their sales volume, by providing them discounts and rebates based upon market share and sales volume. Defendants worked in concert to incentivize purchases of wholesale prescription opioid drugs so that they could decrease their costs per pill and increase their profits. By decreasing volume purchase prices to high volume distributors and pharmacies, Defendants' distributors could maintain prescription opioid drug costs while increasing their profits.

119. Defendants, working clandestinely, incentivized their distributors and pharmacies to boost opioid sales through a series of contractual relationships allowing for the coordination of sales activities, incentives and increased profits.

120. As a result of Defendants' conspiratorial activities and incentives, the sales volume of prescription opioids increased dramatically, along with revenues, with a corresponding increase of illegitimate, improper, and illegal prescription opioids being distributed to the public including in the Plaintiff and surrounding communities.

121. Under constant pressure from Defendants to increase sales, wholesale distributors and pharmacies were directed to sell more opioids, fill more "borderline" or suspicious orders, and increase distribution amounts of opioid based prescription drugs to the point that it was obvious to those taking part in the conspiracy that a large amount of the prescription drug sales could not possibly be legitimate, that there could not be any legitimate medical justification for the skyrocketing opioid sales, and that opioid distribution was exponentially exceeding reasonable limits.

122. Defendants' statutory duties of reporting unusual sales, suspect transactions and unlawful diversion of dangerous controlled substances, were (and are) being ignored. The Defendants and their distributors were on notice from the United States Government that repeated DEA enforcement actions were being conducted in the State of Alabama, and that a vast amount of prescription opioids were being abused and diverted in the State of Alabama, and Defendants' legal obligations to maintain "effective controls" to prevent the illegal sale and distribution of prescription opioid drugs were being ignored and overlooked.

123. Ignoring their legal and statutory duties, Defendants not only disregarded danger signs, but advanced policies and procedures to cover up their illegal (but highly profitable) conduct

in a conspiracy to sell more prescription opioids. In disregard of the facts indicating an opioid epidemic, Defendants have continued their "aggressive marketing" practices.

124. To justify the alarming number of opioids distributed across America and within Alabama, Defendants advanced their conspiracy through the misrepresentation of their products including the public's need for opioids and the lack of legitimate reasons for skyrocketing consumption numbers, including:

a. misrepresenting and misleading the truth behind increasing sales and opioid addiction;

b. misrepresenting that opioids improve patient function;

c. misrepresenting that opioid dependency can be effectively managed;

d. misrepresenting that opioid prescriptions do not create dependency leading to illegal street drug consumption;

e. misrepresenting that opioids should be used for more than very short periods of time, and could be used as treatment or management for chronic pain;

f. misrepresenting, fraudulently suppressing, and/or failing to disclose that Defendants had funded alleged "independent research" to support their misrepresentations and fraudulent claims concerning the effectiveness of opioid derivatives to prevent or minimize addiction risks;

g. misrepresenting that opioid withdrawal could be easily and simply managed;

h. falsely and fraudulently stating that opioid dosage posed no significant risks to patients; and

i. falsely and fraudulently suppressing the serious adverse effects of opioids while overstating the risks and potential complications from use of alternative forms of pain treatment.

125. Defendants' conspiracy has exacted a financial burden for which the Plaintiff seeks relief and damages. Categories of past and continuing sustained damages include, *inter alia*, (1) costs for providing treatment, counseling, and rehabilitation services; (2) costs associated with law enforcement and public safety relating to the opioid epidemic; and (3) costs associated with providing care for children whose parents suffer from opioid-related disability or incapacitation. These damages have been suffered, and continue to be suffered directly, by the Plaintiff.

126. As a direct and proximate result of Defendants' civil conspiracy directed at the general public, including Plaintiff and surrounding community, Plaintiff seeks all damages, including compensatory and punitive, to which it is entitled by law together with attorneys' fees and costs of this action.

COUNT VI
(WANTON-INTENTIONAL CONDUCT & PUNITIVE DAMAGES)

127. All allegations and paragraphs in this complaint are incorporated by reference. To the extent necessary, this cause of action is pleaded in the alternative to the other causes of action.

128. Defendants' actions, separately and severally, are the product of their conscious disregard of the rights and safety of the Plaintiff and its residents, with the attendant awareness that harm will (and has) likely result from Defendants' actions.

129. The actions of Defendants are set forth in the preceding counts and paragraphs of this Complaint and are incorporated herein by reference. Defendants' actions are willful, wanton, intentional and committed with reckless disregard for the safety of Plaintiff and its residents.

130. The conduct of Defendants has been, and continues to be, willful as defined by

Alabama law such that Defendants were aware that their actions, as well as their failure to act in stopping and preventing improper opioid distribution, would cause harm to the public including the Plaintiff and its residents.

131. While Defendants may not have intended harm to the Plaintiff in this case, Defendants knew that breach of their legal duties would cause great harm to the general public and to Alabamians in particular, yet they proceeded in their efforts to distribute and sell prescription opioids in disregard of Plaintiff's health, welfare and safety.

132. The actions of Defendants, separately and severally, have combined and concurred to harm Plaintiff, and the actions of Defendants have all contributed to cause Plaintiff's damages.

133. The actions of Defendants have, and continue to be, carried on with a reckless and/or conscious disregard for the rights, welfare, and safety of the Plaintiff and its residents.

134. The actions of Defendants have, and continue to be, the source of unjust hardship on Plaintiff and its residents.

135. The actions of Defendants have, and continue to be, wrongful actions without just cause or excuse.

136. Plaintiff demands judgment against Defendants in an amount of money that is punitive in nature and is sufficient to punish Defendants for their wrongful conduct and to protect the public by deterring and discouraging Defendants and others from doing the same or similar wrongs in the future.

COUNT VII
(RACKETEER INFLUENCE AND CORRUPT ORGANIZATION ACT, 18 U.S.C. 1961, *et seq.*)

137. All allegations and paragraphs in this complaint are incorporated by reference. To the extent necessary, this cause of action is pleaded in the alternative to the other causes of action.

138. Plaintiff brings this Count against the following Defendants, as defined above: Purdue, Cephalon, Janssen, Endo, Mallinckrodt, Actavis, McKesson, Cardinal, and AmerisourceBergen (collectively, for purposes of this Count, the "RICO Defendants").

139. The RICO Defendants conducted and continue to conduct their business through legitimate and illegitimate means in the form of an association-in-fact enterprise and/or a legal entity enterprise. At all relevant times, the RICO Defendants were "persons" under 18 U.S.C. § 1961(3) because they are entities capable of holding, and do hold, "a legal or beneficial interest in property."

140. Section 1962(c) of RICO makes it unlawful "for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise's affairs through a pattern of racketeering activity or collection of unlawful debt." 18 U.S.C. § 1962(c); *United States v. Turkette*, 452 U.S. 576, 580 (1981).

141. The term "enterprise" includes "any individual, partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact although not a legal entity." 18 U.S.C. § 1961(4); *Turkette*, 452 U.S. at 580; *Boyle v. U.S.*, 556 U.S. 938, 944 (2009). The definition of "enterprise" in Section 1961(4) includes legitimate and illegitimate enterprises within its scope. Specifically, the section "describes two separate categories of associations that come within the purview of an 'enterprise' -- the first encompassing organizations such as corporations, partnerships, and other 'legal entities,' and the second covering 'any union or group of individuals associated in fact although not a legal entity.'" *Turkette*, 452 U.S. at 577. The second category is not a more generalized description of the first. *Id*.

142. For over a decade, the RICO Defendants aggressively sought to bolster their

revenue, increase profit and grow their share of the prescription painkiller market by unlawfully and surreptitiously increasing the volume of opioids they sold. However, the RICO Defendants are not permitted to engage in a limitless expansion of their market through the unlawful sales of regulated painkillers. As "registrants," the RICO Defendants operated and continue to operate within the "closed system" created under the Controlled Substances Act, 21 U.S.C. § 821, *et seq.* (the "CSA"). The CSA restricts the RICO Defendants' ability to manufacture or distribute Schedule II substances like opioids by requiring them to: (1) register to manufacture or distribute opioids; (2) maintain effective controls against diversion of the controlled substances that they manufacturer or distribute; (3) design and operate a system to identify suspicious orders of controlled substances, halt such unlawful sales and report them to the DEA; and (4) make sales within a limited quota set by the DEA for the overall production of Schedule II substances like opioids.

143. Congress specifically intended the closed system created by the CSA, including the establishment of quotas, to reduce or eliminate the diversion of Schedule II substances like opioids from "legitimate channels of trade" to the illicit market by controlling "the quantities of the basic ingredients needed for the manufacture of [controlled substances]."[10]

144. Finding it impossible to legally achieve their sales ambitions, members of the Opioid Diversion Enterprise (as defined below) systematically and fraudulently violated their statutory duty to maintain effective controls against diversion of their drugs, to design and operate a system to identify suspicious orders of their drugs, to halt unlawful sales of suspicious orders

[10] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

and to notify the DEA of suspicious orders.[11] As discussed below, through the RICO Defendants' scheme, members of the Opioid Diversion Enterprise repeatedly engaged in unlawful sales of painkillers, which, in turn, artificially and illegally increased the annual production quotas for opioids allowed by the DEA.[12] As a result, the RICO Defendants allowed hundreds of millions of pills to enter the illicit market, which allowed them to generate obscene profits.

145. An association-in-fact enterprise between the Manufacturer Defendants and the Distributor Defendants planned Defendants' illegal scheme, and the scheme was executed in perfect harmony by each Defendant. In particular, each of the RICO Defendants were associated with and conducted or participated in the affairs of the RICO enterprise (defined below and referred to collectively as the "Opioid Diversion Enterprise"), the purpose of which was to engage in the unlawful sales of opioids, while deceiving the public and federal and state regulators into believing that the RICO Defendants were faithfully fulfilling their statutory obligations. The RICO Defendants' scheme allowed them to make billions in unlawful sales of opioids and, in turn, increase and/or maintain high production quotas with the purpose of ensuring unlawfully increasing revenues, profits and market share. As a direct result of the RICO Defendants' fraudulent scheme, course of conduct and pattern of racketeering activity, they were able to take billions of dollars of revenue from the addicted American public, while entities like the Plaintiff experienced millions of dollars of injury caused by the reasonably foreseeable consequences of the prescription opioid addiction epidemic. As explained below, the RICO Defendants' misconduct violated Section 1962(c), and 18 U.S.C. § 1964(c) entitles Plaintiff to treble damages for its injuries.

[11] 21 U.S.C. § 823(a)(1), (b)(1); 21 C.F.R. § 1301.74(b)-(c).

[12] 21 C.F.R. § 1303.11(b); 21 C.F.R. § 1303.23.

146. The RICO Defendants were members of a legal entity enterprise within the meaning of 18 U.S.C. § 1961(4), through which the RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States. Specifically, the Healthcare Distribution Alliance (the "HDA")[13] is a distinct legal entity that satisfies the definition of a RICO enterprise. The HDA is a non-profit corporation formed under the laws of the District of Columbia and doing business in Virginia. As a non-profit corporation, HDA qualifies as an "enterprise" within the definition set out in 18 U.S.C. § 1961(4) because it is a corporation and a legal entity.

147. Each of the RICO Defendants is a member, participant and/or sponsor of the HDA and utilized the HDA to conduct the Opioid Diversion Enterprise and to engage in the pattern of racketeering activity that gives rise to the Count.

148. Each of the RICO Defendants is a legal entity separate and distinct from the HDA. Additionally, the HDA serves the interests of distributors and manufacturers beyond the RICO Defendants. Therefore, the HDA exists separately from the Opioid Diversion Enterprise, and each of the RICO Defendants exists separately from the HDA. Therefore, the HDA may serve as a RICO enterprise.

149. The legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs were each used by the RICO Defendants to conduct the Opioid Diversion Enterprise by engaging in a pattern of racketeering activity. Therefore, the legal and association-in-fact enterprises alleged in the previous and subsequent paragraphs are pleaded in the alternative and are collectively referred to as the "Opioid Diversion Enterprise."

[13] Health Distribution Alliance, *History*, Health Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history.

A. THE OPIOID DIVERSION ENTERPRISE.

150. The United States Congress enacted the Controlled Substances Act in 1970.[14] The CSA and its implementing regulations created a closed system of distribution for all controlled substances and listed chemicals.[15] Congress specifically designed the closed chain of distribution to prevent the diversion of legally produced controlled substances into the illicit market.[16] As reflected in comments from United States Senators during deliberation on the CSA, the "[CSA] is designed to crack down hard on the narcotics pusher and the illegal diverters of pep pills and goof balls."[17] Congress was concerned with the diversion of drugs out of legitimate channels of distribution when it enacted the CSA and acted to halt the "widespread diversion of [controlled substances] out of legitimate channels into the illegal market."[18] Moreover, Congress specifically designed the closed system to ensure that there are multiple ways of identifying and preventing diversion through active participation by registrants within the drug delivery chain.[19] All registrants – manufacturers and distributors alike – must adhere to the specific security, recordkeeping, monitoring and reporting requirements that are designed to identify or prevent

[14] Joseph T. Rannazzisi Decl. ¶ 4, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12- cv-185 (Document 14-2 February 10, 2012).

[15] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566.

[16] *Gonzalez v. Raich*, 545 U.S. 1, 12-14 (2005); 21 U.S.C. § 801(20; 21 U.S.C. §§ 821-824, 827, 880; H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. 4566, 4572 (Sept. 10, 1970).

[17] *See* H.R. Rep. No. 91-1444, 1970 U.S.C.C.A.N. at 4566; 116 Cong. Rec. 977-78 (Comments of Sen. Dodd, Jan 23, 1970).

[18] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

[19] See Statement of Joseph T. Rannazzisi before the Caucus on International Narcotics Control United States Senate, July 18, 2012 (available at https://www.justice.gov/sites/default/files/testimonies/witnesses/attachments/07/18/12/07-18-12-dea-rannazzisi.pdf).

diversion.[20] When registrants at any level fail to fulfill their obligations, the necessary checks and balances collapse.[21] The result is the scourge of addiction that has occurred.

151. In 2006 and 2007, the DEA issued multiple letters to the Distributor Defendants reminding them of their obligation to maintain effective controls against diversion of particular controlled substances, design and operate a system to disclose suspicious orders, and inform the DEA of any suspicious orders.[22] The DEA also published suggested questions that a distributor should ask prior to shipping controlled substances, in order to "know their customers."[23]

152. Central to the closed system created by the CSA was the directive that the DEA determine quotas of each basic class of Schedule I and II controlled substances each year. The quota system was intended to reduce or eliminate diversion from "legitimate channels of trade" by controlling the "quantities of the basic ingredients needed for the manufacture of [controlled substances] and requiring order forms for all transfers of these drugs."[24] When evaluating production quotas, the DEA was instructed to consider the following information:

a. Information provided by the Department of Health and Human Services;

b. Total net disposal of the basic class by all manufacturers;

c. Trends in the national rate of disposal of the basic class;

d. An applicant's production cycle and current inventory position;

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[20] *Id.*

[21] Joseph T. Rannazzisi Decl. ¶ 10, *Cardinal Health, Inc. v. Eric Holder, Jr., Attorney General*, D.D.C. Case No. 12-cv-185 (Document 14-2 February 10, 2012).

[22] Joseph T. Rannazzisi, *In Reference to Registration # RC0183080 (September 27, 2006)*; Joseph T. Rannazzisi, In Reference to Registration # RC0183080 (December 27, 2007).

[23] *Suggested Questions a Distributor Should Ask Prior to Shipping Controlled Substances*, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf).

[24] 1970 U.S.C.C.A.N. 4566 at 5490; *see also* Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).

e. Total actual or estimated inventories of the class and of all substances manufactured from the class and trends in inventory accumulation; and

f. Other factors such as: changes in the currently accepted medical use of substances manufactured for a basic class; the economic and physical availability of raw materials; yield and sustainability issues; potential disruptions to production; and unforeseen emergencies.[25]

153. It is unlawful for a registrant to manufacture a controlled substance in Schedule II, like prescription opioids, that is (1) not expressly authorized by its registration and by a quota assigned to it by DEA or (2) in excess of a quota assigned to it by the DEA.[26]

154. At all relevant times, the RICO Defendants operated as an association-in-fact enterprise formed for the purpose of unlawfully increasing sales, revenues and profits by disregarding their statutory duty to identify, investigate, halt and report suspicious orders of opioids and diversion of their drugs into the illicit market in order to unlawfully increase the quotas set by the DEA and allow them to collectively benefit from the unlawful formation of a greater pool of prescription opioids from which to profit. The RICO Defendants conducted their pattern of racketeering activity in this jurisdiction and throughout the United States through this enterprise.

155. The opioid epidemic has its origins in the mid-1990s when, between 1997 and 2007, per capita purchase of methadone, hydrocodone and oxycodone increased 13-fold, 4-fold and 9-fold, respectively. By 2010, enough prescription opioids were sold in the United States to medicate every adult in the country with a dose of 5 milligrams of hydrocodone every 4 hours for 1

[25] See Testimony of Joseph T. Rannazzisi before the Caucus on International Narcotics Control, United States Senate, May 5, 2015 (available at https://www.drugcaucus.senate.gov/sites/default/files/Rannazzisi%20Testimony_0.pdf).
[26] *Id.* (citing 21 U.S.C. 842(b)).

month.[27] On information and belief, the Opioid Diversion Enterprise has been ongoing for at least the last decade.[28]

156. The Opioid Diversion Enterprise has been conducting business uninterrupted since its inception. However, it was not until recently that United States and State regulators finally began to unravel the extent of the enterprise and the toll that it exacted on the American public. At all relevant times, the Opioid Diversion Enterprise: (a) had an existence separate and distinct from each RICO Defendant; (b) was separate and distinct from the pattern of racketeering in which the RICO Defendants engaged; (c) was an ongoing and continuing organization consisting of legal entities, including each of the RICO Defendants; (d) was characterized by interpersonal relationships among the RICO Defendants; (e) had sufficient longevity for the enterprise to pursue its purpose; and (f) functioned as a continuing unit. *Turkette*, 452 U.S. at 580; *Boyle*, 556 U.S. at 944 (2009). Each member of the Opioid Diversion Enterprise participated in the conduct of the enterprise, including patterns of racketeering activity, and shared in the astounding growth of profits supplied by fraudulently inflating opioid sales generated as a result of the Opioid Diversion Enterprise's disregard for their duty to prevent diversion of their drugs into the illicit market and requests that the DEA increase production quotas, all so that the RICO Defendants would have a larger pool of prescription opioids from which to profit.

157. The Opioid Diversion Enterprise also engaged in efforts to lobby against the DEA's authority to hold the RICO Defendants liable for disregarding their duty to prevent diversion. Members of the Pain Care Forum (described in greater detail below) and the Healthcare

[27] Keyes KM, Cerdá M, Brady JE, Havens JR, Galea S. *Understanding the rural-urban differences in nonmedical prescription opioid use and abuse in the United States*, Am J Public Health. 2014;104(2):e52-9.

[28] Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo- chamber-shaped-policy-amid-drug-epidemic.

Distribution Alliance lobbied for the passage of legislation to weaken the DEA's enforcement authority. The Ensuring Patient Access and Effective Drug Enforcement Act significantly reduced the DEA's ability to issue orders to show cause and to suspend and/or revoke registrations.[29] The HDA and other members of the Pain Care Forum contributed substantial amounts of money to political campaigns for federal candidates, state candidates, political action committees and political parties. Plaintiff is informed and believes that the Pain Care Forum and its members poured millions into lobbying efforts in this jurisdiction while the HDA devoted over a million dollars a year to its lobbying efforts between 2011 and 2016.

158. The Opioid Diversion Enterprise functioned by selling prescription opioids. While there are some legitimate uses and/or needs for prescription opioids, the RICO Defendants, through their illegal enterprise, engaged in a pattern of racketeering activity that involves a fraudulent scheme to increase revenue by violating State and Federal laws requiring the maintenance of effective controls against diversion of prescription opioids and the identification, investigation and reporting of suspicious orders of prescription opioids destined for the illicit drug market. The goal of Defendants' scheme was to increase profits from opioid sales. However, Defendants' profits were limited by the production quotas set by the DEA, so the Defendants refused to identify, investigate and/or report suspicious orders of their prescription opioids being diverted into the illicit drug market. The end result of this strategy was to increase and maintain artificially high

[29] *See HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea- slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13- d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

production quotas of opioids so that there was a larger pool of opioids for Defendants to manufacture and distribute for public consumption.

159. The Opioid Diversion Enterprise engaged in, and its activities affected, interstate and foreign commerce because the enterprise involved commercial activities across state lines, such as manufacture, sale, distribution and shipment of prescription opioids throughout the country and this jurisdiction and the corresponding payment and/or receipt of money from the sale of the same.

160. The Opioid Diversion Enterprise used its interpersonal relationships and common communication by which the RICO Defendants shared information on a regular basis. These interpersonal relationships also formed the organization of the Opioid Diversion Enterprise. The Opioid Diversion Enterprise used their interpersonal relationships and communication network for the purpose of conducting the enterprise through a pattern of racketeering activity.

161. Each of the RICO Defendants had a systematic link to each other through joint participation in lobbying groups, trade industry organizations, contractual relationships and continuing coordination of activities. The RICO Defendants participated in the operation and management of the Opioid Diversion Enterprise by directing its affairs, as described herein.

162. The RICO Defendants exerted substantial control over the Opioid Diversion Enterprise by their membership in the Pain Care Forum and the HDA and through their contractual relationships.

163. The Pain Care Forum ("PCF") is a coalition of drug makers, trade groups and dozens of non-profit organizations supported by industry funding. The PCF recently became a national news story when reporters discovered that lobbyists for members of the PCF quietly shaped federal and state policies regarding the use of prescription opioids for more than a decade.

164. The Center for Public Integrity and The Associated Press obtained "internal documents shed[ding] new light on how drug makers and their allies shaped the national response to the ongoing wave of prescription opioid abuse."[30] Specifically, PCF members spent over $740 million lobbying in the nation's capital and in all 50 statehouses on an array of issues, including opioid-related measures.[31]

165. Not surprisingly, each of the RICO Defendants who stood to profit from lobbying in favor of prescription opioid use is a member of and/or participant in the PCF.[32] In 2012, membership and participating organizations included the HDA (of which all RICO Defendants are members), Endo, Purdue, Johnson & Johnson (the parent company for Janssen Pharmaceuticals), Actavis (*i.e.*, Allergan) and Teva (the parent company of Cephalon).[33] Each of the Manufacturer Defendants worked together through the PCF to advance the interests of the enterprise. However, the Manufacturer Defendants were not alone. The Distributor Defendants actively participated and continue to participate in the PCF, at a minimum, through their trade organization, the HDA.[34] Plaintiff is informed and believes that the Distributor Defendants participated directly in the PCF as well.

166. The 2012 Meeting Schedule for the Pain Care Forum is particularly revealing on

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[30] Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity (September 19, 2017, 12:01 a.m.), https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo- chamber-shaped-policy-amid-drug-epidemic.

[31] *Id.*

[32] *Pain Care Forum 2012 Meetings Schedule*, (last updated December 2011), https://assets.documentcloud.org/documents/3108982/PAIN-CARE-FORUM-Meetings-Schedule-amp.pdf.

[33] *Id*. Based on information and belief, Mallinckrodt became an active member of the PCF sometime after 2012.

[34] *Id*. The Executive Committee of the HDA (formerly the HDMA) currently includes the Chief Executive Officer, Pharmaceutical Segment for Cardinal Health, Inc., the Group President, Pharmaceutical Distribution and Strategic Global Source for AmerisourceBergen Corporation, and the President, U.S. Pharmaceutical for McKesson Corporation. Executive Committee, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/executive-committee.

the subject of the Defendants' interpersonal relationships. The meeting schedule indicates that meetings were held in the D.C. office of Powers Pyles Sutter & Verville on a monthly basis, unless otherwise noted. Local members were "encouraged to attend in person."

167. The 2012 Pain Care Forum Meeting Schedule demonstrates that each of the Defendants participated in meetings on a monthly basis either directly or through their trade organization, in a coalition of drug makers and their allies, the sole purpose of which was to shape the national response to the ongoing prescription opioid epidemic, including the concerted lobbying efforts that the PCF undertook on behalf of its members.

168. Second, the HDA – or Healthcare Distribution Alliance – led to the formation of interpersonal relationships and an organization between the RICO Defendants. Although the entire HDA membership directory is private, the HDA website confirms that each of the Distributor Defendants and the Manufacturer Defendants named in the Complaint, including Actavis (*i.e.*, Allergan), Endo, Purdue, Mallinckrodt and Cephalon, were members of the HDA.[35] Additionally, the HDA and each of the Distributor Defendants eagerly sought the active membership and participation of the Manufacturer Defendants by advocating that one of the benefits of membership included the ability to develop direct relationships between Manufacturers and Distributors at high executive levels.

169. In fact, the HDA touted the benefits of membership to the Manufacturer Defendants, advocating that membership included the ability to "network one on one with manufacturer executives at HDA's members-only Business and Leadership Conference," "networking with HDA wholesale distributor members," "opportunities to host and sponsor HDA

[35] *Manufacturer Membership*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/membership/manufacturer.

Board of Directors events," "participate on HDA committees, task forces and working groups with peers and trading partners" and "make connections."[36] The HDA and the Distributor Defendants believed that membership in the HDA was an opportunity to create interpersonal and ongoing organizational relationships between the Manufacturers and Defendants.

170. The application for manufacturer membership in the HDA further indicates the level of connection that existed between the RICO Defendants.[37] A "senior company executive" must sign the manufacturer membership application, and it requests that the manufacturer applicant identify a key contact and any additional contacts from within its company. The HDA application also requests that the manufacturer identify its current distribution information and its most recent year-end net sales through any HDA distributors, including, but not limited to, Defendants AmerisourceBergen, Cardinal Health and McKesson.[38]

171. After becoming members, the Distributors and Manufacturers were eligible to participate on councils, committees, task forces, and working groups. The councils, committees, task forces, and working groups provided the Manufacturer and Distributor Defendants with the opportunity to work closely together in shaping their common goals and forming the enterprise's organization. The HDA also offers a multitude of conferences, including annual business and leadership conferences. The HDA and the Distributor Defendants advertise these conferences to the Manufacturer Defendants as an opportunity to "bring together high-level executives, thought leaders and influential managers… to hold strategic business discussions on the most pressing

[36] *Manufacturer Membership Benefits*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-benefits.ashx?la=en.

[37] *Manufacturer Membership Application*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/~/media/pdfs/membership/manufacturer-membership-application.ashx?la=en.

[38] *Id*.

industry issues."[39] The conferences also gave the Manufacturer and Distributor Defendants "unmatched opportunities to network with [their] peers and trading partners at all levels of the healthcare distribution industry."[40] The HDA and its conferences were significant opportunities for the Manufacturer and Distributor Defendants to interact at a high level of leadership. It is clear that the Manufacturer Defendants embraced this opportunity by attending and sponsoring these events.[41]

172. Third, the RICO Defendants maintained their interpersonal relationships by working together, exchanging information and driving the unlawful sales of their opioids through their contractual relationships, including chargebacks and vault security programs.

173. The Manufacturer Defendants engaged in an industry-wide practice of paying rebates and/or chargebacks to the Distributor Defendants for sales of prescription opioids.[42] As reported in the Washington Post, identified by Senator McCaskill and acknowledged by the HDA, there is an industry-wide practice whereby the Manufacturers paid the Distributors rebates and/or chargebacks on their prescription opioid sales.[43] On information and belief, these contracts were negotiated at the highest levels, demonstrating ongoing relationships between the Manufacturer

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[39] *Business and Leadership Conference – Information for Manufacturers*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-business-and-leadership- conference/blc-for-manufacturers.

[40] *Id*.

[41] *2015 Distribution Management Conference and Expo*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/events/2015-distribution-management-conference.

[42] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356; *see also*, Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letter from Sen. Claire McCaskill, (July 27, 2017), https://www.mccaskill.senate.gov/imo/media/image/july-opioid-investigation-letter-manufacturers.png; Letters From Sen. Claire McCaskill, (March 28, 2017), https://www.mccaskill.senate.gov/opioid-investigation; *Purdue Managed Markets*, Purdue Pharma, http://www.purduepharma.com/payers/managed-markets/.

[43] *Id.*

and Distributor Defendants. In return for the rebates and chargebacks, the Distributor Defendants provided the Manufacturer Defendants with detailed information regarding their prescription opioid sales, including purchase orders, acknowledgements, ship notices, and invoices.[44] The Manufacturer Defendants used this information to gather high-level data regarding overall distribution and direct the Distributor Defendants on how to most effectively sell the prescription opioids.

174. The contractual relationships among the RICO Defendants also include vault security programs. The RICO Defendants are required to maintain certain security protocols and storage facilities for the manufacture and distribution of their opiates. Plaintiff is informed and believes that Manufacturers negotiated agreements whereby the Manufacturers installed security vaults for Distributors in exchange for agreements to maintain minimum sales performance thresholds. Plaintiff is informed and believes that these agreements were used by the RICO Defendants as a tool to violate their reporting and diversion duties in order to reach the required sales requirements.

175. Taken together, the interaction and length of the relationships between and among the Manufacturer and Distributor Defendants reflects a deep level of interaction and cooperation between two groups in a tightly knit industry. The Manufacturer and Distributor Defendants were not two separate groups operating in isolation or two groups forced to work together in a closed system. The RICO Defendants operated together as a united entity, working together on multiple fronts, to engage in the unlawful sale of prescription opioids. The HDA and the Pain Care Forum are but two examples of the overlapping relationships, and concerted joint efforts to accomplish common goals and demonstrates that the leaders of each of the RICO Defendants were in

[44] *Webinars*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/resources/webinar-leveraging-edi.

communication and cooperation.

176. According to articles published by the Center for Public Integrity and The Associated Press, the Pain Care Forum – the members of which include the Manufacturers and the Distributors' trade association – has been lobbying on behalf of the Manufacturers and Distributors for "more than a decade."[45] From 2006 to 2016, the Distributors and Manufacturers worked together through the Pain Care Forum to spend over $740 million lobbying in the nation's capital and in all 50 statehouses on issues including opioid-related measures. Similarly, the HDA has continued its work on behalf of Distributors and Manufacturers, without interruption, since at least 2000, if not longer.[46]

177. The RICO Defendants began working together as early as 2006 through the Pain Care Forum and/or the HDA to promote the common purpose of their enterprise. Plaintiff is informed and believes that the RICO Defendants worked together as an ongoing and continuous organization throughout the existence of their enterprise.

B. CONDUCT OF THE OPIOID DIVERSION.

178. During the time period alleged in this Complaint, the RICO Defendants exerted control over, conducted, and/or participated in the Opioid Diversion Enterprise by fraudulently failing to comply with their Federal and State obligations to identify, investigate and report suspicious orders of opioids in order to prevent diversion of those highly addictive substances into the illicit market and to halt such unlawful sales so as to increase production quotas and generate unlawful profits, as follows:

[45] Matthew Perrone, *Pro-Painkiller echo chamber shaped policy amid drug epidemic*, The Center for Public Integrity, https://www.publicintegrity.org/2016/09/19/20201/pro-painkiller-echo- chamber-shaped-policy-amid-drug-epidemic.

[46] *HDA History*, Healthcare Distribution Alliance, https://www.healthcaredistribution.org/about/hda-history.

179. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to maintain effective controls against diversion of their prescription opioids.

180. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligations to design and operate a system to disclose to the registrant suspicious orders of their prescription opioids.

181. Defendants disseminated false and misleading statements to the public claiming that they were complying with their obligation to notify the DEA of any suspicious orders or diversion of their prescription opioids.

182. Defendants paid nearly $800 million dollars to influence local, state and federal governments through joint lobbying efforts as part of the Pain Care Forum. The RICO Defendants were all members of the Pain Care Forum either directly or indirectly through the HDA. The lobbying efforts of the Pain Care Forum and its members included efforts to pass legislation making it more difficult for the DEA to suspend and/or revoke the Manufacturers' and Distributors' registrations for failure to report suspicious orders of opioids.

183. The RICO Defendants exercised control and influence over the distribution industry by participating and maintaining membership in the HDA.

184. The RICO Defendants applied political and other pressure on the DOJ and DEA to halt prosecutions for failure to report suspicious orders of prescription opioids and lobbied Congress to strip the DEA of its ability to immediately suspend registrations pending investigation

by passing the "Ensuring Patient Access and Effective Drug Enforcement Act."[47]

185. The RICO Defendants engaged in an industry-wide practice of paying rebates and chargebacks to incentivize unlawful opioid prescription sales. Plaintiff is informed and believes that the Manufacturer Defendants used the chargeback program to acquire detailed, high-level data regarding sales of the opioids they manufactured. Additionally, Plaintiff is informed and believes that the Manufacturer Defendants used this high-level information to direct the Distributor Defendants' sales efforts to regions where prescription opioids were selling in larger volumes.

186. The Manufacturer Defendants lobbied the DEA to increase Aggregate Production Quotas year after year by submitting net disposal information that the Manufacturer Defendants knew included sales that were suspicious and involved the diversion of opioids the RICO Defendants had not properly investigated or reported.

187. The Distributor Defendants developed "know your customer" questionnaires and files. This information, compiled pursuant to comments from the DEA in 2006 and 2007, was intended to help the RICO Defendants identify suspicious orders or customers who were likely to divert prescription opioids.[48] On information and belief, the "know your customer" questionnaires

[47] *See HDMA is now the Healthcare Distribution Alliance*, Pharmaceutical Commerce, (June 13, 2016, updated July 6, 2016), http://pharmaceuticalcommerce.com/business-and-finance/hdma-now-healthcare-distribution-alliance/; Lenny Bernstein & Scott Higham, *Investigation: The DEA Slowed Enforcement While the Opioid Epidemic Grew Out of Control*, Wash. Post, Oct. 22, 2016, https://www.washingtonpost.com/investigations/the-dea- slowed-enforcement-while-the-opioid-epidemic-grew-out-of-control/2016/10/22/aea2bf8e-7f71-11e6-8d13- d7c704ef9fd9_story.html; Lenny Bernstein & Scott Higham, *Investigation: U.S. Senator Calls for Investigation of DEA Enforcement Slowdown Amid Opioid Crisis*, Wash. Post, Mar. 6, 2017, https://www.washingtonpost.com/investigations/us-senator-calls-for-investigation-of-dea-enforcement-slowdown/2017/03/06/5846ee60-028b-11e7-b1e9-a05d3c21f7cf_story.html; Eric Eyre, *DEA Agent: "We Had no Leadership" in WV Amid Flood of Pain Pills*, Charleston Gazette-Mail, Feb. 18, 2017, http://www.wvgazettemail.com/news/20170218/dea-agent-we-had-no-leadership-in-wv-amid-flood-of-pain-pills-.

[48] *Suggested Questions a Distributor should ask prior to shipping controlled substances*, Drug Enforcement Administration (available at https://www.deadiversion.usdoj.gov/mtgs/pharm_industry/14th_pharm/levinl_ques.pdf); Richard Widup, Jr., Kathleen H. Dooley, Esq. *Pharmaceutical Production Diversion: Beyond the PDMA*, Purdue Pharma and McQuite Woods LLC, (available at https://www.mcguirewoods.com/news-resources/publications/lifesciences/product_diversion_beyond_pdma.pdf).

informed the RICO Defendants of the number of pills that the pharmacies sold, how many non-controlled substances they sold compared to controlled substances, whether the pharmacy buys from other distributors, and the types of medical providers in the area, including pain clinics, general practitioners, hospice facilities, cancer treatment facilities, among others, and these questionnaires put the recipients on notice of suspicious orders.

188. The RICO Defendants refused to identify, investigate, and report suspicious orders to the DEA when they became aware of the same despite their actual knowledge of drug diversion rings. The RICO Defendants refused to identify suspicious orders and diverted drugs despite the DEA issuing final decisions against the Distributor Defendants in 178 registrant actions between 2008 and 2012[49] and 117 recommended decisions in registrant actions from The Office of Administrative Law Judges. These numbers include 76 actions involving orders to show cause and 41 actions involving immediate suspension orders -- all for failure to report suspicious orders.[50]

189. Defendants' scheme had a decision-making structure driven by the Manufacturer Defendants and corroborated by the Distributor Defendants. The Manufacturer Defendants worked together to control the State and Federal Government's response to the manufacture and distribution of prescription opioids by increasing production quotas through a systematic refusal to maintain effective controls against diversion and identify suspicious orders and report them to the DEA.

190. The RICO Defendants worked together to control the flow of information and influence state and federal governments and political candidates to pass legislation that was pro-opioid. The Manufacturer and Distributor Defendants did this through their participation in the

[49] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

[50] *Id.*

Pain Care Forum and Healthcare Distributors Alliance.

191. The RICO Defendants also worked together to ensure that the Aggregate Production Quotas, Individual Quotas and Procurement Quotas allowed by the DEA stayed high and ensured that suspicious orders were not reported to the DEA. By not reporting orders or diversion of prescription opioids, the RICO Defendants ensured that the DEA had no basis for refusing to increase or decrease the production quotas for prescription opioids due to diversion of suspicious orders. The RICO Defendants influenced the DEA production quotas in the following ways:

a. The Distributor Defendants assisted the enterprise and the Manufacturer Defendants in their lobbying efforts through the Pain Care Forum;

b. The Distributor Defendants invited the participation, oversight and control of the Manufacturer Defendants by including them in the HDA, including on the councils, committees, task forces and working groups;

c. The Distributor Defendants provided sales information to the Manufacturer Defendants regarding their prescription opioids, including reports of all opioid prescriptions filled by the Distributor Defendants;

d. The Manufacturer Defendants used a chargeback program to ensure delivery of the Distributor Defendants' sales information;

e. The Manufacturer Defendants obtained sales information from QuintilesIMS (formerly IMS Health) that gave them a "stream of data showing how individual doctors across the nation were prescribing

opioids."[51]

f. The Distributor Defendants accepted rebates and chargebacks for orders of prescription opioids;

g. The Manufacturer Defendants used the Distributor Defendants' sales information and the data from QuintilesIMS to instruct the Distributor Defendants to focus their distribution efforts to specific areas where the purchase of prescription opioids was most frequent;

h. The RICO Defendants identified suspicious orders of prescription opioids and then continued filling those unlawful orders, without reporting them, knowing that they were suspicious and/or being diverted into the illicit drug market;

i. The RICO Defendants refused to report suspicious orders of prescription opioids despite repeated investigation and punishment of the Distributor Defendants by the DEA for failure to report suspicious orders; and

j. The RICO Defendants withheld information regarding suspicious orders and illicit diversion from the DEA because it would have revealed that the "medical need" for and the net disposal of their drugs did not justify the production quotas set by the DEA.

192. The scheme the RICO Defendants devised and implemented amounted to a common course of conduct characterized by a refusal to maintain effective controls against diversion, and all designed and operated to ensure the continued unlawful sale of controlled

[51] Harriet Ryan, *et al.*, *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

substances.

C. PATTERN OF RACKETEERING ACTIVITY.

193. The RICO Defendants conducted and participated in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(B), including mail fraud (18 U.S.C. § 1341) and wire fraud (18 U.S.C. § 1343) and (18 U.S.C. § 1961(D)) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

1. The RICO Defendants Engaged in Mail and Wire Fraud.

194. The RICO Defendants carried out, or attempted to carry out, a scheme to defraud federal and state regulators and the American public by knowingly conducting or participating in the conduct of the Opioid Diversion Enterprise through a pattern of racketeering activity within the meaning of 18 U.S.C. § 1961(1) that employed the use of mail and wire facilities, in violation of 18 U.S.C. § 1341 (mail fraud) and § 1343 (wire fraud).

195. The RICO Defendants committed, conspired to commit, and/or aided and abetted in the commission of at least two predicate acts of racketeering activity (*i.e.,* violations of 18 U.S.C. §§ 1341 and 1343) within the past ten years. The multiple acts of racketeering activity that the RICO Defendants committed, or aided and abetted in the commission of, were related to each other, posed a threat of continued racketeering activity, and therefore constitute a "pattern of racketeering activity." The racketeering activity was made possible by the RICO Defendants' regular use of the facilities, services, distribution channels, and employees of the Opioid Diversion Enterprise. The RICO Defendants participated in the scheme to defraud by using mail, telephone, and the internet to transmit mailings and wires in interstate or foreign commerce.

196. The RICO Defendants used, directed the use of, and/or caused to be used thousands of interstate mail and wire communications in service of their scheme through virtually uniform misrepresentations, concealments, and material omissions regarding their compliance with their mandatory reporting requirements and the actions necessary to carry out their unlawful goal of selling prescription opioids without reporting suspicious orders or the diversion of opioids into the illicit market.

197. In devising and executing the illegal scheme, the RICO Defendants devised and knowingly carried out a material scheme and/or artifice to defraud by means of materially false or fraudulent pretenses, representations, promises, or omissions of material facts. For the purpose of executing the illegal scheme, the RICO Defendants committed these racketeering acts, which number in the thousands, intentionally and knowingly with the specific intent to advance the illegal scheme.

198. The RICO Defendants' predicate acts of racketeering (18 U.S.C. § 1961(1)) include, but are not limited to:

a. Mail Fraud: The RICO Defendants violated 18 U.S.C. § 1341 by sending or receiving, or by causing to be sent and/or received, materials via U.S. mail or commercial interstate carriers for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by means of false pretenses, misrepresentations, promises and omissions.

b. Wire Fraud: The RICO Defendants violated 18 U.S.C. § 1343 by transmitting and/or receiving, or by causing to be transmitted and/or received, materials by wire for the purpose of executing the unlawful scheme to design, manufacture, market, and sell the prescription opioids by

means of false pretenses, misrepresentations, promises, and omissions.

199. The RICO Defendants' use of the mail and wires includes, but is not limited to, Manufacturers, Distributors, or third parties that were foreseeably caused to conduct the transmission, delivery, or shipment of the following as a result of the RICO Defendants' illegal scheme, including but not limited to:

a. The prescription opioids;

b. Documents and communications that facilitated the manufacture, purchase, and unlawful sale of prescription opioids;

c. Defendants' DEA registrations;

d. Documents and communications that supported and/or facilitated Defendants' DEA registrations;

e. Documents and communications that supported and/or facilitated the Defendants' request for higher aggregate production quotas, individual production quotas, and procurement quotas;

f. Defendants' records and reports that 21 U.S.C. § 827 required Defendants to submit to the DEA;

g. Documents and communications related to the Defendants' mandatory DEA reports pursuant to 21 U.S.C. § 823 and 21 C.F.R. § 1301.74;

h. Documents intended to facilitate the manufacture and distribution of Defendants' prescription opioids, including bills of lading, invoices, shipping records, reports, and correspondence;

i. Documents for processing and receiving payment for prescription opioids;

j. Payments from the Distributors to the Manufacturers;

k. Rebates and chargebacks from the Manufacturers to the Distributors;

l. Payments to Defendants' lobbyists through the Pain Care Forum;

m. Payments to Defendants' trade organizations, like the HDA, for memberships and/or sponsorships;

n. Deposits of proceeds from Defendants' manufacture and distribution of prescription opioids; and

o. Other documents and things, including electronic communications.

200. On information and belief, the RICO Defendants (and/or their agents), for the purpose of executing the illegal scheme, sent and/or received (or caused to be sent and/or received) shipments of prescription opioids and related documents by mail or by private carrier affecting interstate commerce, including the following:

a. Purdue manufactures multiple forms of prescription opioids, including, but not limited to: OxyContin, MS Contin, Dilaudid/Dilaudid HP, Butrans, Hysingla ER, and Targiniq ER. Purdue manufactured and shipped these prescription opioids to the Distributor Defendants.

b. The Distributor Defendants shipped Purdue's prescription opioids throughout this jurisdiction.

c. Cephalon manufactures multiple forms of prescription opioids, including, but not limited to: Actiq and Fentora. Cephalon manufactured and shipped these prescription opioids to the Distributor Defendants.

d. The Distributor Defendants shipped Cephalon's prescription opioids throughout this jurisdiction.

e. Janssen manufactures a prescription opioid known as Duragesic. Janssen

manufactured and shipped its prescription opioids to the Distributor Defendants.

f. The Distributor Defendants shipped Janssen's prescription opioids throughout this jurisdiction.

g. Endo manufactures multiple forms of prescription opioids, including, but not limited to: Opana/Opana ER, Percodan, Percocet, and Zydone. Endo manufactured and shipped its prescription opioids to the Distributor Defendants in the State.

h. The Distributor Defendants shipped Endo's prescription opioids throughout this jurisdiction.

i. Actavis manufactures multiple forms of prescription opioids, including, but not limited to: Kadian and Norco, as well as generic versions of the drugs known as Kadian, Duragesic, and Opana. Actavis manufactured and shipped its prescription opioids to the Distributor Defendants.

j. The Distributor Defendants shipped Actavis' prescription opioids throughout this jurisdiction.

k. Mallinckrodt manufactures multiple forms of prescription opioids, including, but not limited to: Exalgo and Roxicodone.

l. The Distributor Defendants shipped Mallinckrodt's prescription opioids throughout this jurisdiction.

201. The RICO Defendants also used the internet and other electronic facilities to carry out their scheme and conceal the ongoing fraudulent activities. Specifically, the RICO Defendants made misrepresentations about their compliance with Federal and State laws requiring them to

identify, investigate, and report suspicious orders of prescription opioids and/or diversion of the same into the illicit market.

202. At the same time, the RICO Defendants misrepresented the superior safety features of their order monitoring programs, ability to detect suspicious orders, commitment to preventing diversion of prescription opioids and their compliance with all state and federal regulations regarding the identification and reporting of suspicious orders of prescription opioids. Plaintiff is also informed and believes that the RICO Defendants utilized the internet and other electronic resources to exchange communications, to exchange information regarding prescription opioid sales and to transmit payments and rebates/chargebacks.

203. The RICO Defendants also communicated by U.S. Mail, by interstate facsimile and by interstate electronic mail with each other and various other affiliates, regional offices, regulators, distributors, and other third-party entities in furtherance of the scheme.

204. The mail and wire transmissions described herein were made in furtherance of Defendants' scheme and common course of conduct to deceive regulators and the public that Defendants were complying with their state and federal obligations to identify and report suspicious orders of prescription opioids, all while Defendants were knowingly allowing millions of doses of prescription opioids to divert into the illicit drug market. The RICO Defendants intended their scheme and common course of conduct to increase or maintain high production quotas for their prescription opioids from which they could profit.

205. Many of the precise dates of the fraudulent uses of the U.S. mail and interstate wire facilities have been deliberately hidden, and cannot be alleged without access to Defendants' books and records. Plaintiff has described the types of and, in some instances, occasions on which the predicate acts of mail and/or wire fraud occurred. They include thousands of communications to

perpetuate and maintain the scheme, including the things and documents described in the preceding paragraphs.

206. The RICO Defendants did not undertake the practices described herein in isolation, but as part of a common scheme. These actions violate 18 U.S.C. § 1962(c). Various other persons, firms and corporations, including third-party entities and individuals not named as defendants in this Complaint, may have contributed to and/or participated in the scheme with the RICO Defendants in these offenses and have performed acts in furtherance of the scheme to increase revenues, increase market share, and /or minimize the losses for the RICO Defendants.

207. The RICO Defendants aided and abetted others in the violations of the above laws, thereby rendering them indictable as principals in the 18 U.S.C. §§ 1341 and 1343 offenses.

208. The RICO Defendants hid from the general public and suppressed and/or ignored warnings from third parties, whistleblowers, and governmental entities the reality of the suspicious orders that the RICO Defendants were filling on a daily basis -- leading to the diversion of tens of millions of doses of prescription opioids into the illicit market.

209. The RICO Defendants, with knowledge and intent, agreed to the overall objective of their fraudulent scheme and participated in the common course of conduct to commit acts of fraud and indecency in manufacturing and distributing prescription opioids.

210. Indeed, for the Defendants' fraudulent scheme to work, each of the Defendants had to agree to implement similar tactics regarding marketing prescription opioids and refusing to report suspicious orders.

211. As described herein, the RICO Defendants engaged in a pattern of related and continuous predicate acts for years. The predicate acts constituted a variety of unlawful activities, each conducted with the common purpose of obtaining significant monies and revenue from the

sale of their highly addictive and dangerous drugs. The predicate acts also had the same or similar results, participants, victims, and methods of commission. The predicate acts were related and not isolated events.

212. The predicate acts all had the purpose of generating significant revenue and profits for the RICO Defendants, while Plaintiff was left with substantial injury to its business through the damage that the prescription opioid epidemic caused. The RICO Defendants committed or caused to be committed the predicate acts through their participation in the Opioid Diversion Enterprise and in furtherance of its fraudulent scheme.

213. The pattern of racketeering activity alleged herein and the Opioid Diversion Enterprise are separate and distinct from each other. Likewise, Defendants are distinct from the enterprise.

214. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

215. RICO Defendants have hidden many of the precise dates of the criminal actions at issue here, and these cannot be alleged without access to Defendants' books and records. Indeed, an essential part of the successful operation of the Opioids Addiction and Opioid Diversion Enterprise alleged herein depended upon secrecy.

216. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission, and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff.

217. Defendants calculated and intentionally crafted the Opioid Diversion Enterprise and their scheme to increase and maintain their increased profits, without regard to the effect such

behavior would have on consumers in this jurisdiction, its citizens or the Plaintiff. In designing and implementing the scheme, at all times Defendants were cognizant of the fact that those in the manufacturing and distribution chain rely on the integrity of the pharmaceutical companies and ostensibly neutral third parties to provide objective and reliable information regarding Defendants' products and their manufacture and distribution of those products. The Defendants were also aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system and to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

218. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

219. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

220. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

2. The RICO Defendants Manufactured, Sold, and/or Dealt in Controlled Substances and Their Crimes are Punishable as Felonies.

221. The RICO Defendants conducted and participated in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity as defined in 18 U.S.C. § 1961(D) by the felonious manufacture, importation, receiving, concealment, buying, selling, or otherwise dealing in a controlled substance or listed chemical (as defined in section 102 of the Controlled Substance Act), punishable under any law of the United States.

222. The RICO Defendants committed crimes that are punishable as felonies under the

laws of the United States. Specifically, 21 U.S.C. § 483(a)(4) makes it unlawful for any person to knowingly or intentionally furnish false or fraudulent information in, or omit any material information from, any application, report, record or other document required to be made, kept or filed under this subchapter. A violation of section 483(a)(4) is punishable by up to four years in prison, making it a felony. 21 U.S.C. § 483(d)(1).

223. Each of the RICO Defendants qualifies as a registrant under the CSA. Their status as registrants under the CSA requires that they maintain effective controls against diversion of controlled substances in schedule I or II, design and operate a system to disclose to the registrant suspicious orders of controlled substances, and inform the DEA of suspicious orders when discovered by the registrant. 21 U.S.C. § 823; 21 C.F.R. § 1301.74(b).

224. The CSA and the Code of Federal Regulations required the RICO Defendants to make reports to the DEA of any suspicious orders identified through the design and operation of their system to disclose suspicious orders.

225. The RICO Defendants knowingly and intentionally furnished false or fraudulent information in their reports to the DEA about suspicious orders and/or omitted material information from reports, records, and other documents they were required to file with the DEA, including the Manufacturer Defendants' applications for production quotas. Specifically, the RICO Defendants were aware of suspicious orders of prescription opioids and the diversion of their prescription opioids into the illicit market and failed to report this information to the DEA in their mandatory reports and their applications for production quotas.

226. In 2013, the DEA and DOJ began investigating McKesson regarding its monitoring and reporting of suspicious controlled substances orders. On April 23, 2015, McKesson filed a Form 8-K announcing a settlement with the DEA and DOJ wherein it admitted to violating the

CSA and agreed to pay $150 million and have some of its DEA registrations suspended on a staggered basis. The settlement was finalized on January 17, 2017.[52]

227. Purdue's experience in Los Angeles is another example of Defendants' willful violation of the CSA and Code of Federal Regulations as they relate to reporting suspicious orders of prescription opioids. In 2016, the Los Angeles Times reported that Purdue was aware of a pill mill operating out of Los Angeles, yet failed to alert the DEA.[53] The Los Angeles Times uncovered that Purdue began tracking a surge in prescriptions in Los Angeles, including one prescriber in particular. A Purdue sales manager spoke with company officials in 2009 about the prescriber, asking "Shouldn't the DEA be contacted about this?" and adding that she felt "very certain this is an organized drug ring."[54] Despite knowledge of the staggering amount of pills being issued in Los Angeles, and internal discussion of the problem, "Purdue did not shut off the supply of highly addictive OxyContin and did not tell authorities what it knew about Lake Medical until several years later when the clinic was out of business and its leaders indicted. By that time, 1.1 million pills had spilled into the hands of Armenian mobsters, the Crips gang and other criminals."[55]

228. Finally, Mallinckrodt was recently the subject of a DEA and Senate investigation for its opioid practices. Specifically, in 2011, the DEA targeted Mallinckrodt, arguing that it ignored its responsibility to report suspicious orders as 500 million of its pills ended up in Florida

[52] McKesson, *McKesson Finalizes Settlement with U.S. Department of Justice and U.S. Drug Enforcement Administration to Resolve Past Claims*, About McKesson / Newsroom / Press Releases, (January 17, 2017), http://www.mckesson.com/about-mckesson/newsroom/press-releases/2017/mckesson-finalizes-settlement-with-doj- and-dea-to-resolve-past-claims/.

[53] Harriet Ryan, *et al*., *More than 1 million OxyContin pills ended up in the hands of criminals and addicts. What the drugmaker knew*, Los Angeles Times, (July 10, 2016), http://www.latimes.com/projects/la-me-oxycontin-part2/.

[54] *Id.*

[55] *Id.*

between 2008 and 2012.[56] After six years of DEA investigation, Mallinckrodt agreed to a settlement involving a $35 million fine. Federal prosecutors summarized the case by saying that Mallinckrodt's response was that everyone knew what was going on in Florida, but they had no duty to report it.[57]

229. The foregoing examples reflect the RICO Defendants' pattern and practice of willfully and intentionally omitting information from their mandatory reports to the DEA as required by 21 C.F.R. § 1301.74. This conclusion is supported by the volume of enforcement actions available in the public records again the Distributor Defendants.[58]

230. These actions against the Distributor Defendants confirm that the Distributor Defendants knew they had a duty to maintain effective controls against diversion, design and operate a system to disclose suspicious orders, and to report suspicious orders to the DEA. These actions also demonstrate, on information and belief, that the Manufacturer Defendants were aware of the enforcement against their Distributors and the diversion of the prescription opioids and a corresponding duty to report suspicious orders.

231. The pattern of racketeering activity alleged herein is continuing as of the date of this Complaint and, upon information and belief, will continue into the future unless enjoined by this Court.

232. Many of the precise dates of Defendants' criminal actions at issue herein were hidden and cannot be alleged without access to Defendants' books and records. Indeed, an essential

[56] Lenny Bernstein & Scott Higham, *The government's struggle to hold opioid manufacturers accountable*, The Washington Post, (April 2, 2017), https://www.washingtonpost.com/graphics/investigations/dea-mallinckrodt/?utm_term=.b24cc81cc356. This number accounted for 66% of all oxycodone sold in the state of Florida during that time.
[57] *Id.*

[58] Evaluation and Inspections Div., Office of the Inspector Gen., U.S. Dep't of Justice, *The Drug Enforcement Administration's Adjudication of Registrant Actions* 6 (2014), https://oig.justice.gov/reports/2014/e1403.pdf.

part of the successful operation of the Opioid Diversion Enterprise depended upon the secrecy of the participants in that enterprise.

233. Each instance of racketeering activity alleged herein was related, had similar purposes, involved the same or similar participants and methods of commission and had similar results affecting similar victims, including consumers in this jurisdiction and the Plaintiff. Defendants calculated and intentionally crafted the diversion scheme to increase and maintain profits from unlawful sales of opioids, without regard to the effect such behavior would have on this jurisdiction, its citizens or the Plaintiff. The Defendants were aware that Plaintiff and the citizens of this jurisdiction rely on the Defendants to maintain a closed system of manufacturing and distribution to protect against the non-medical diversion and use of their dangerously addictive opioid drugs.

234. By intentionally refusing to report and halt suspicious orders of their prescription opioids, Defendants engaged in a fraudulent scheme and unlawful course of conduct constituting a pattern of racketeering activity.

235. It was foreseeable to Defendants that refusing to report and halt suspicious orders, as required by the CSA and Code of Federal Regulations, would harm Plaintiff by allowing the flow of prescription opioids from appropriate medical channels into the illicit drug market.

236. The last racketeering incident occurred within five years of the commission of a prior incident of racketeering.

D. DAMAGES

237. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's injury because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

238. Defendants' racketeering activities proximately caused Plaintiff's injuries and those of its citizens. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

239. The RICO Defendants' racketeering activities directly caused Plaintiff's injuries and those of its citizens.

240. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

241. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia,* actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit, and pre- and post-judgment interest.

COUNT VIII
(RACKETEER INFLUENCE AND CORRUPT ORGANIZATION ACT, 18 U.S.C. 1962(d), *et seq.*)

242. All allegations and paragraphs in this complaint are incorporated by reference. To the extent necessary, this cause of action is pleaded in the alternative to the other causes of action.

243. Plaintiff brings this claim on its own behalf against all RICO Defendants. At all relevant times, the RICO Defendants were associated with the Opioid Diversion Enterprise and agreed and conspired to violate 18 U.S.C. § 1962(c), that is, they agreed to conduct and participate, directly and indirectly, in the conduct of the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity in violation of 18 U.S.C. § 1962(d). Under Section 1962(d), it is unlawful for "any person to conspire to violate" Section 1962(d), among other provisions. 18 U.S.C. § 1962(d).

244. Defendants conspired to violate Section 1962(c), as alleged more fully above, by

conducting the affairs of the Opioid Diversion Enterprise through a pattern of racketeering activity, as incorporated by reference below.

A. THE OPIOID DIVERSION ENTERPRISE.

245. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Opioid Diversion Enterprise."

B. CONDUCT OF THE OPIOID DIVERSION ENTERPRISE.

246. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Conduct of the Opioid Diversion Enterprise."

C. PATTERN OF RACKETEERING ACTIVITY.

247. For efficiency and avoiding repetition, for purposes of this claim, Plaintiff incorporates by reference the paragraphs set out above concerning the "Pattern of Racketeering Activity."

D. DAMAGES.

248. The RICO Defendants' violations of law and their pattern of racketeering activity directly and proximately caused Plaintiff's injury because Plaintiff paid for costs associated with the opioid epidemic, as described above in allegations expressly incorporated herein by reference.

249. The RICO Defendants' racketeering activities proximately caused Plaintiff's injuries and those of its citizens. But for the RICO Defendants' conduct, Plaintiff would not have paid the health services and law enforcement services and expenditures required as a result of the plague of drug-addicted residents.

250. The RICO Defendants' racketeering activities directly caused Plaintiff's injuries

and those of its citizens.

251. Plaintiff was most directly harmed and there is no other Plaintiff better suited to seek a remedy for the economic harms at issue here.

252. Plaintiff seeks all legal and equitable relief as allowed by law, including, *inter alia*, actual damages, treble damages, equitable relief, forfeiture as deemed proper by the Court, attorneys' fees and all costs and expenses of suit and pre- and post-judgment interest.

RELIEF

WHEREFORE, in consideration of the claims stated above, Plaintiff in this case respectfully submits that upon a full hearing of the evidence that this Honorable Court, and the jury hearing this case, grant the following relief.

253. Judgment in favor of the Plaintiff against each Defendant separately and severally, based on joint and several liability, against each and every Defendant in this case.

254. An entry of equitable relief and Order of Abatement against Defendants, jointly and severally, along with all those acting in concert with Defendants including all agents, subsidiaries and all other persons acting in concert or participation with Defendants from continuing the conduct made the subject of this Complaint.

255. An Order of Injunction against Defendants on a permanent basis along with accompanying restitution.

256. An Order from this Court against Defendants that they fully compensate Plaintiff for past and future expenses required to abate the nuisance caused by the opioid epidemic, including an Order requiring Defendants to fund an "abatement fund" for the purposes of abating the opioid nuisance.

257. A judgment and award of compensatory damages, including without limitation, all

damages previously outlined in this Complaint along with:

a. costs for providing emergency response services;

b. costs for law enforcement, corrections and correctional facilities expenses;

c. all costs incurred by the Plaintiff, directly and/or indirectly, of county and municipal judicial services, including prosecutors, court costs, court personnel, public defender services and related expenses;

d. all costs for public welfare subsistence and related agencies;

e. all costs associated for providing health insurance, rehabilitation services and any other employment benefits to Plaintiff's employees and family members related to opioid use, abuse and/or addiction;

f. all other reimbursement damages to compensate Plaintiff for costs relating to the opioid epidemic including loss of tax revenue, losses sustained from the payment of opioid related damages that could have put to other public services;

g. an award of punitive damages against the Defendants in an amount that sets an example to deter similar wrongful corporate behavior in the future; and

258. In addition to the damages outlined herein, Plaintiff demands that Defendants pay court costs, including attorneys' fees, applicable interest and all other relief as allowed under Alabama law and as this Court deems appropriate and just.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury.

Dated: May 29, 2018

Respectfully submitted,

Counsel for Plaintiff

s/Brad Ponder
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